

US3712114 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:27:55

All time stamps listed in this document are displayed in GMT

US3712114

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 00:23:31

Generated On: 10 Jun 2021 09:27:55

Participant ID

US3712114

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

US3712114

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
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

US3712114

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Date of Informed Consent (<i>dd MMM yyyy</i>)	16 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

US3712114

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3712114

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Were any significant conditions reported?

Yes ☒

No ☐

US3712114

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	ALLERGY TO PENICILLIN
Start date (dd MMM yyyy)	UN UNK 1956
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 1956
Start Year (derived)	1956
Stop Month and Year (derived)	
Stop Year (derived)	

US3712114

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	ANISOMETROPIA
Start date (dd MMM yyyy)	UN UNK 1964
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 1964
Start Year (derived)	1964
Stop Month and Year (derived)	
Stop Year (derived)	

US3712114

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	WISDOM TEETH IMPACTION
Start date (dd MMM yyyy)	UN UNK 1972
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 1972
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	JAN 1972
Stop Year (derived)	1972

US3712114

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	WISDOM TEETH EXTRACTION
Start date (dd MMM yyyy)	UN UNK 1972
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 1972
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	JAN 1972
Stop Year (derived)	1972

US3712114

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	JAN 1975
Stop Year (derived)	1975

US3712114

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	JAN 1975
Stop Year (derived)	1975

US3712114

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	NASAL SEPTUM DEVIATION
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	JAN 1980
Stop Year (derived)	1980

US3712114

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	LEFT SKULL FRACTURE
Start date (dd MMM yyyy)	UN UNK 1969
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 1969
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1969
Start Year (derived)	1969
Stop Month and Year (derived)	JAN 1969
Stop Year (derived)	1969

US3712114

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	LEFT SKULL FRACTURE
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	JAN 1975
Stop Year (derived)	1975

US3712114

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	
Stop Year (derived)	

US3712114

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3712114

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	SARCOIDOSIS
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

US3712114

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	DIABETES MELLITUS TYPE 2
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	
Stop Year (derived)	

US3712114

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	DIABETIC NEUROPATHY BILATERAL
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3712114

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	HEMATOMA LEFT ANKLE
Start date (dd MMM yyyy)	UN UNK 1973
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 1973
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1973
Start Year (derived)	1973
Stop Month and Year (derived)	JAN 1973
Stop Year (derived)	1973

US3712114

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	HEMATOMA LEFT ANKLE REMOVED
Start date (dd MMM yyyy)	UN UNK 1973
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 1973
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1973
Start Year (derived)	1973
Stop Month and Year (derived)	JAN 1973
Stop Year (derived)	1973

US3712114

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	LEFT ELBOW FRACTURE
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3712114

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	LEFT ELBOW SURGICAL REPAIR
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3712114

Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	14 JUL 2020
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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3712114

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 10:40
Height (xxx.x)	174.0 cm
Weight (xxx.x)	95.3 kg
BMI (xxx.x)	31.47708 kg/m ²
BMI units	KG/M2
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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3712114

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3712114

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

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 PLACE OF WORSHIP, CHURCH.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

US3712114

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

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	

US3712114

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3712114

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

What was the date of randomization? (dd MMM yyyy) 24 SEP 2020

What was the participant's randomization number? 191284

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 ☒

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Height	173.0 cm
Weight	96.6 kg

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Height	173.0 cm
Weight	96.6 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)	24 SEP 2020
Time of assessment (00:00-23:59)	09:20 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 09:20
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Height	173.0 cm
Weight	96.6 kg
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	12:10 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 12:10
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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3712114

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3712114

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 11:40 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 11:40

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

US3712114

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 SEP 2020
Collection time (00:00-23:59)	09:30 (24 HR)
Collection date and time (derived)	24 SEP 2020 09:30

US3712114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 17:13:08

Generated On: 10 Jun 2021 09:27:55

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:35	24 SEP 2020 09:35
Nasopharyngeal Swab 2	No		

US3712114

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

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

24 SEP 2020 12:12

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 14:30

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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 95.8 °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	24 SEP 2020 20:26
PC Open Date & Time	24 SEP 2020 15:25
PC Close Date & Time	25 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °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

25 SEP 2020 22:36

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

26 SEP 2020 23:44

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:27:55

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

97.0 °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

27 SEP 2020 22:06

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:27:55

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

97.1 °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

29 SEP 2020 00:01

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °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

30 SEP 2020 00:00

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:27:55

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

97.7 °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

30 SEP 2020 21:43

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

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

24 SEP 2020 12:13

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 14:30

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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

24 SEP 2020 20:27

PC Open Date & Time

24 SEP 2020 15:25

PC Close Date & Time

25 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

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

25 SEP 2020 22:39

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

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

26 SEP 2020 23:45

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

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

27 SEP 2020 22:06

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

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

29 SEP 2020 00:01

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

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

30 SEP 2020 00:01

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

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

30 SEP 2020 21:44

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 12:14
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 14:30

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 20:27
PC Open Date & Time	24 SEP 2020 15:25
PC Close Date & Time	25 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

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 ☒

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 22:41
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

70 of 2565

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 23:45
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

72 of 2565

EAB) (1725)

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 22:07
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

74 of 2565

EAB) (1725)

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 00:02
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

76 of 2565

EAB) (1725)

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 00:01
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

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

78 of 2565

EAB) (1725)

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 21:44
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3712114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 01 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3712114

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712114

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3712114

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712114

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3712114

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712114

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	09:57 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 09:57
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)	65 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)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 11:15
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3712114

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

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.

US3712114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 22 OCT 2020

What was the treatment time? (00:00-23:59) 10:45 (24 HR)

Treatment Date and Time (derived) 22 OCT 2020 10:45

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

What was the frequency of the study treatment dosing? ONCE

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

US3712114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 OCT 2020
Collection time (00:00-23:59)	10:10 (24 HR)
Collection date and time (derived)	22 OCT 2020 10:10

US3712114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 17:13:08

Generated On: 10 Jun 2021 09:27:55

Collection date (dd MMM yyyy)			22 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:12	22 OCT 2020 10:12
Nasopharyngeal Swab 2	No		

US3712114

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 11:37

PC Open Date & Time

22 OCT 2020 11:05

PC Close Date & Time

22 OCT 2020 13:35

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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 97.4 °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	22 OCT 2020 20:58
PC Open Date & Time	22 OCT 2020 14:30
PC Close Date & Time	23 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:27:55

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

97.6 °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

23 OCT 2020 22:38

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 OCT 2020 00:09

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:27:55

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

97.1 °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

25 OCT 2020 22:09

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:27:55

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

97.1 °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

26 OCT 2020 23:04

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

27 OCT 2020 22:02

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 OCT 2020 21:20

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 OCT 2020 11:34

PC Open Date & Time

22 OCT 2020 11:05

PC Close Date & Time

22 OCT 2020 13:35

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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

22 OCT 2020 20:59

PC Open Date & Time

22 OCT 2020 14:30

PC Close Date & Time

23 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

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

23 OCT 2020 22:39

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

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

25 OCT 2020 00:10

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

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

25 OCT 2020 22:09

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 OCT 2020 23:05

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 OCT 2020 22:02

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 OCT 2020 21:20

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

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

No ☒

Yes ☐

PC Time stamp	22 OCT 2020 11:35
PC Open Date & Time	22 OCT 2020 11:05
PC Close Date & Time	22 OCT 2020 13:35

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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

No ☒

Yes ☐

PC Time stamp	22 OCT 2020 21:00
PC Open Date & Time	22 OCT 2020 14:30
PC Close Date & Time	23 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

114 of 2565

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

Yes <input type="checkbox"/>	
PC Time stamp	23 OCT 2020 22:41
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

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 ☒

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

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 ☒

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 22:10
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

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 ☒

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 23:05
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

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 ☒

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 22:03
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

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)

124 of 2565

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

Yes <input type="checkbox"/>	
PC Time stamp	28 OCT 2020 21:20
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3712114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3712114

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712114

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712114

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712114

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3712114

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712114

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

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) _____

US3712114

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

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.

US3712114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 NOV 2020
Collection time (00:00-23:59)	11:22 (24 HR)
Collection date and time (derived)	24 NOV 2020 11:22

US3712114

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:28:13

Generated On: 10 Jun 2021 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT	DAY 61
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	21 NOV 2020 17:03:45
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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	30 NOV 2020 04:42:58
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 00:07:56

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 <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	13 DEC 2020 14:57:36
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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	19 DEC 2020 00:02:21
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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	26 DEC 2020 13:21:44
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 15:55:12

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 00:08:50
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 JAN 2021 14:30:21

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 11:33:00

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

30 JAN 2021 00:02:33

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

08 FEB 2021 12:01:00

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 12:55:52
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 16:38:07

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 12:49:09

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

09 MAR 2021 11:49:34

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

13 MAR 2021 19:04:37

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 11:09:19

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

27 MAR 2021 00:02:41

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

03 APR 2021 00:02:34

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

11 APR 2021 15:17:49

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

17 APR 2021 00:35:06

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

26 APR 2021 12:00:40

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

01 MAY 2021 10:48:47

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 243

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

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

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

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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="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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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="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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 <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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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="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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	24 NOV 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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="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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	05 JAN 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 <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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 607

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

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

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

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

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

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 663

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

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

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

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

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

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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="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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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="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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 <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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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"/>

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:27:55

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 12:49:49

US3712114

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 02:32:20

Generated On: 10 Jun 2021 09:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712114

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 02:32:20

Generated On: 10 Jun 2021 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712114

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:07:44

Generated On: 10 Jun 2021 09:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712114

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:07:44

Generated On: 10 Jun 2021 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712114

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:07:44

Generated On: 10 Jun 2021 09:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712114

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:07:44

Generated On: 10 Jun 2021 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712114

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:07:44

Generated On: 10 Jun 2021 09:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712114

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:07:44

Generated On: 10 Jun 2021 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712114

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

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 _____

US3712114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

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)	

US3712114

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:55

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.

US3712114

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

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/>

US3712114

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3712114

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:27:55

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"/>

US3712114

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:27:55

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3712114

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 00:07:43

Generated On: 10 Jun 2021 09:27:55

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

Visit date (dd MMM yyyy)	01 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3712114

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 00:07:43

Generated On: 10 Jun 2021 09:27:55

Date of updated informed consent (<i>dd MMM yyyy</i>)	01 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	01 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3712114

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 00:07:43

Generated On: 10 Jun 2021 09:27:55

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3712114

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 00:07:43

Generated On: 10 Jun 2021 09:27:55

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 FEB 2021
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	01 FEB 2021 09:05
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)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3712114

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 00:07:43

Generated On: 10 Jun 2021 09:27:55

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 FEB 2021
Time of assessment (00:00-23:59)	10:24 (24 HR)
Vital Signs Date and Time (derived)	01 FEB 2021 10:24
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3712114

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 00:23:32

Generated On: 10 Jun 2021 09:27:55

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.

US3712114

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 00:23:32

Generated On: 10 Jun 2021 09:27:55

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 01 FEB 2021

What was the treatment time? (00:00-23:59) 09:54 (24 HR)

Treatment Date and Time (derived) 01 FEB 2021 09:54

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

US3712114

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 00:23:32

Generated On: 10 Jun 2021 09:27:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 FEB 2021

Collection time (00:00-23:59)

08:56 (24 HR)

Collection date and time (derived)

01 FEB 2021 08:56

US3712114

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 00:23:32

Generated On: 10 Jun 2021 09:27:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 FEB 2021
Collection time (00:00 - 23:59)	08:59
Collection Date and Time (derived)	01 FEB 2021 08:59

US3712114

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:23:32

Generated On: 10 Jun 2021 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712114

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:07:44

Generated On: 10 Jun 2021 09:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712114

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:07:44

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 00:23:32

Generated On: 10 Jun 2021 09:27:55

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

Visit date (dd MMM yyyy)	02 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 00:23:32

Generated On: 10 Jun 2021 09:27:55

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)	02 MAR 2021
Time of assessment (00:00-23:59)	08:08 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 08:08
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 00:23:32

Generated On: 10 Jun 2021 09:27:55

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 MAR 2021
Time of assessment (00:00-23:59)	09:21 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 09:21
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 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)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3712114

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 00:23:32

Generated On: 10 Jun 2021 09:27:55

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.

US3712114

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 00:23:32

Generated On: 10 Jun 2021 09:27:55

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 02 MAR 2021

What was the treatment time? (00:00-23:59) 08:51 (24 HR)

Treatment Date and Time (derived) 02 MAR 2021 08:51

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

US3712114

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:23:32

Generated On: 10 Jun 2021 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712114

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:07:44

Generated On: 10 Jun 2021 09:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712114

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:07:44

Generated On: 10 Jun 2021 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712114

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

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 _____

US3712114

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

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)	

US3712114

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:55

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.

US3712114

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

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/>

US3712114

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 22:22:21

Generated On: 10 Jun 2021 09:27:55

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 21:40:30

Generated On: 10 Jun 2021 09:27:55

AEID	USA-US068-2021-MRNA-1273-P30 1000012
Adverse event	PROGRESSION PROSTATE CANCER
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)	01 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	14 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	366 of 2565

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 21:40:30

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 21:40:30

Generated On: 10 Jun 2021 09:27:55

HAD LABS DONE THAT
RESULTED IN ABNORMAL PSA.
PCP SENT THEM TO HAVE
PROSTATE BIOPSY ON 14 JULY
2020 THAT SHOWED STAGE 1
AND 2 PROSTATE CANCER.
SUBJECT STATES THEY HAVE
NOT HAD ANY MEDICATION
AND DEFERRED RADIATION,
BUT IS HAVING A
PROSTATECTOMY ON 13
NOVEMBER 2020.

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

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 00:23:32

Generated On: 10 Jun 2021 09:27:55

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

Yes ☒

No ☐

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

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

370 of 2565

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	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 1989	
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"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication GLYXAMBI

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 25-5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

372 of 2565

EAB) (1725)

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	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 1989
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"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication MUCINEX DM

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1200/60

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

374 of 2565

EAB) (1725)

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication LORATADINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

376 of 2565

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

378 of 2565

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	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 1989
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"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

380 of 2565

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	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 1989
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication ESOMEPRAZOLE MAGNESIUM

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

382 of 2565

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2000	
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"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication TRESIBA INSULIN PEN

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 16

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

384 of 2565

EAB) (1725)

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 2

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

If dose unit is Other, specify GUMMIES

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

386 of 2565

EAB) (1725)

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	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"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication DIABETIC NEUROPATHY

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

388 of 2565

EAB) (1725)

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

390 of 2565

EAB) (1725)

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	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"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication OMEGA 3 KRILL OIL

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

392 of 2565

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication IRON

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 65

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

394 of 2565

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication OXYCODONE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF PAIN AFTER
SURGERY 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

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

396 of 2565

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	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)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF INFECTION
AFTER SURGERY WHILE
HOSPITALIZED

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 ☐

PRODUCTION RELEASE (v12.003

398 of 2565

EAB) (1725)

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	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)		13 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF PAIN AFTER
SURGERY WHILE
HOSPITALIZED

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)

400 of 2565

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	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)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication ZOFRAN

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

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

402 of 2565

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	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)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF PAIN AFTER
SURGERY WHILE
HOSPITALIZED

Dose per administration 975

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)

404 of 2565

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	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)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF DEEP VEIN
THROMBOSIS WHILE
HOSPITALIZED

Dose per administration 5000

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 8 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

406 of 2565

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	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)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication OXYBUTYNIN

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF BLADDER
SPASMS AFTER SURGERY
WHILE HOSPITALIZED

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

408 of 2565

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	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)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
DEHYDRATION WHILE
HOSPITALIZED

Dose per administration 880.4

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

410 of 2565

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	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)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication LISPRO INSULIN

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 4

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

If dose unit is Other, specify U

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

412 of 2565

EAB) (1725)

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	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)		14 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication PROTONIX (PANTOPRAZOLE
SODIUM,CALCIUM STEARATE,
CROSPVIDONE,HYPROMELLO
SE,IRON
OXIDE,MANNITOL,
METHACRYLIC ACID
COPOLYMER,POLYSORBATE
80,POVIDONE,PROPYLENE
GLYCOL,SODIUM
CARBONATE,TRIETHYL
CITRATE)

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
GASTROESOPHAGEAL REFLUX
DISEASE WHILE HOSPITALIZED

Dose per administration 40

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

If dose unit is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

414 of 2565

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	once	<input checked="" type="radio"/>
	unknown	<input type="radio"/>
	other	<input type="radio"/>

If frequency is Other, specify

Route of administration

Oral	<input checked="" type="radio"/>
Topical	<input type="radio"/>
Subcutaneous	<input type="radio"/>
Transdermal	<input type="radio"/>
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 type="radio"/>

If route of administration is Other, specify

Start date (dd MMM yyyy) 14 NOV 2020

Start date completely unknown False

Ongoing? Yes ☐
No ☒

If not Ongoing, End date (dd MMM yyyy) 14 NOV 2020

Was this medication taken for solicited event? Yes ☐
No ☒

Separate Dosage Number (derived)

Interval Dosage Unit Number (derived)

Interval Dosage Definition (derived) 802 ☐
803 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

415 of 2565

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

804 ☐

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication PHENAZOPYRIDINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF PAINFUL
URINATION AFTER SURGERY
WHILE HOSPITALIZED

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

417 of 2565

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	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)		13 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

Name of Medication CHOLECALCIFEROL

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 5000

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

419 of 2565

EAB) (1725)

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

	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)		14 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 14 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3712114

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 00:23:32

Generated On: 10 Jun 2021 09:27:55

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3712114

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Apr 2021 00:23:32

Generated On: 10 Jun 2021 09:27:55

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 NOV 2020	ROBOTIC ASSISTED LAPAROSCOPIC RADIAL PROSTATECTOMY WITH BILATERAL PELVIC LYMPH NODE DISSECTION	Adverse Event	

US3712114

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:27:55

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

US3712114

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:27:55

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 ☐

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

SAEID	USA-US068-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

SAEID	USA-US068-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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)	17/FEB/2021 07:58
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

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

SAEID	USA-US068-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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 15:12
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

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

SAEID	USA-US068-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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)	08/MAR/2021 10:38
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

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

SAEID	USA-US068-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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)	13/APR/2021 15:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Apr 2021 21:40:31

Generated On: 10 Jun 2021 09:27:55

SAEID	USA-US068-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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)	22/APR/2021 14:17
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

Audit

US3712114 (Prod: Alliance for Multispecialty Research, LLC)

US3712114

Form: Participant Creation

Generated On: 10 Jun 2021 09:27:55

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered 'US3712114'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 13:54:44

US3712114

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:13:50

US3712114

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '16 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 13:54:45

US3712114

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:13:50

US3712114

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'SCRN'	System	17 Sep 2020 12:13:50

US3712114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 13:54:46

US3712114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:27:55

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '70'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:14:43

US3712114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:27:55

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'YEARS'	System	17 Sep 2020 12:14:43

US3712114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:27:55

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '70'	System	17 Sep 2020 12:14:57

US3712114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:27:55

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:14:43

US3712114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:27:55

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:14:43

US3712114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:27:55

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:14:43

US3712114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:27:55

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:14:43

US3712114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:27:55

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:14:43

US3712114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:27:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:14:43

US3712114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:27:55

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:14:43

US3712114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:27:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:14:43

US3712114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:27:55

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:14:43

US3712114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:27:55

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:14:43

US3712114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:27:55

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:14:43

US3712114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:27:55

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:14:57

US3712114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Sep 2020'	System	17 Sep 2020 12:14:57

US3712114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '2020'	System	17 Sep 2020 12:14:57

US3712114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:27:55

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:14:57

US3712114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	24 Sep 2020 15:52:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 05:01:46
Query 'Data is required. Please complete.' answered with 'waiting to be dosed before fully enrolling subject' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 12:15:45
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 12:14:57
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 12:14:57

US3712114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:14:57

US3712114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:27:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:14:57

US3712114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:27:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:14:57

US3712114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:27:55

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 13:54:45

US3712114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:27:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'I'	System	24 Sep 2020 15:52:32

US3712114

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:52:32

US3712114

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:27:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:40

US3712114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:27:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:21:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:21:53
Data point term sent to Coder	System	28 Sep 2020 18:21:07
User entered 'allergy to penicillin'	(b) (4), (b) (6)	28 Sep 2020 18:21:00

US3712114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1956'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:21:00

US3712114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:21:00

US3712114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:21:00

US3712114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:21:00

US3712114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:21:00

US3712114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1956'	System	28 Sep 2020 18:21:00

US3712114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1956'	System	28 Sep 2020 18:21:00

US3712114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:21:00

US3712114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:21:00

US3712114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:27:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:23:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:23:41
Data point term sent to Coder	System	28 Sep 2020 18:22:09
User entered 'allergy to sulfa'	(b) (4), (b) (6)	28 Sep 2020 18:21:13

US3712114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1958'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:21:13

US3712114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:21:13

US3712114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:21:13

US3712114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:21:13

US3712114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:21:13

US3712114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1958'	System	28 Sep 2020 18:21:13

US3712114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1958'	System	28 Sep 2020 18:21:13

US3712114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:21:13

US3712114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:21:13

US3712114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:27:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User coded data point as SOC: Investigations, HLGT: Immunology and allergy investigations, HLT: Immunoglobulin analyses, PT: Immunoglobulins, LLT: Immunoglobulins - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:32:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:32:40
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User closed query 'Per MM, please clarify the MH term ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 13:07:25
Query 'Per MM, please clarify the MH term ' answered with 'updating' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 14:58:36
User opened query 'Per MM, please clarify the MH term ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 21:38:38
User closed query 'Per CDM: per sponsor review please confirm with PI to update term to 'antitetanic Immunoglobulins from animal origin' as the condition is recorded as ongoing and update accordingly' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 18:24:51
Data point term sent to Coder	System	29 Jan 2021 17:49:52
Query 'Per CDM: per sponsor review please confirm with PI to update term to 'antitetanic Immunoglobulins from animal origin' as the condition is recorded as ongoing and update accordingly' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 17:49:18
Coding entries removed.	(b) (4), (b) (6)	29 Jan 2021 17:49:13
User entered 'antitetanic Immunoglobulins from animal origin' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 17:49:13
User opened query 'Per CDM: per sponsor review please confirm with PI to update term to 'antitetanic Immunoglobulins from animal origin' as the condition is recorded as ongoing and update accordingly' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 09:45:43

US3712114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:27:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Allergy to vaccine, LLT: Allergy to vaccine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 18:59:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 18:59:38
Data point term sent to Coder	System	28 Sep 2020 18:23:09
User entered 'allergy to tetanus vaccine with horse derivative'	(b) (4), (b) (6)	28 Sep 2020 18:22:15

US3712114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1958'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:22:15

US3712114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:22:15

US3712114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:22:15

US3712114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:22:15

US3712114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:22:15

US3712114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1958'	System	28 Sep 2020 18:22:15

US3712114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1958'	System	28 Sep 2020 18:22:15

US3712114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:22:15

US3712114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:22:15

US3712114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Anisometropia, LLT: Anisometropia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:23:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:23:42
Data point term sent to Coder	System	28 Sep 2020 18:23:11
User entered 'anisometropia'	(b) (4), (b) (6)	28 Sep 2020 18:22:41

US3712114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1964'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:22:41

US3712114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:22:41

US3712114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:22:41

US3712114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:22:41

US3712114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:22:41

US3712114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1964'	System	28 Sep 2020 18:22:41

US3712114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1964'	System	28 Sep 2020 18:22:41

US3712114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:22:41

US3712114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:22:41

US3712114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:27:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental disorders NEC, PT: Tooth impacted, LLT: Impacted wisdom tooth - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:23:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:23:42
Data point term sent to Coder	System	28 Sep 2020 18:23:10
User entered 'wisdom teeth impaction'	(b) (4), (b) (6)	28 Sep 2020 18:23:01

US3712114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1972'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:01

US3712114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:01

US3712114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:01

US3712114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1972'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:01

US3712114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:01

US3712114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1972'	System	28 Sep 2020 18:23:01

US3712114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1972'	System	28 Sep 2020 18:23:01

US3712114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1972'	System	28 Sep 2020 18:23:01

US3712114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1972'	System	28 Sep 2020 18:23:01

US3712114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Wisdom teeth removal, LLT: Wisdom teeth removal - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:24:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:24:47
Data point term sent to Coder	System	28 Sep 2020 18:24:11
User entered 'wisdom teeth extraction'	(b) (4), (b) (6)	28 Sep 2020 18:23:15

US3712114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1972'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:15

US3712114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:15

US3712114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:15

US3712114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1972'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:15

US3712114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:15

US3712114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1972'	System	28 Sep 2020 18:23:15

US3712114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1972'	System	28 Sep 2020 18:23:15

US3712114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1972'	System	28 Sep 2020 18:23:15

US3712114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1972'	System	28 Sep 2020 18:23:15

US3712114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:27:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:24:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:24:48
Data point term sent to Coder	System	28 Sep 2020 18:24:12
User entered 'tonsillitis'	(b) (4), (b) (6)	28 Sep 2020 18:23:39

US3712114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1975'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:39

US3712114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:39

US3712114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:39

US3712114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1975'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:39

US3712114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:39

US3712114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1975'	System	28 Sep 2020 18:23:39

US3712114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1975'	System	28 Sep 2020 18:23:39

US3712114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1975'	System	28 Sep 2020 18:23:39

US3712114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1975'	System	28 Sep 2020 18:23:39

US3712114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:24:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:24:48
Data point term sent to Coder	System	28 Sep 2020 18:24:13
User entered 'tonsillectomy'	(b) (4), (b) (6)	28 Sep 2020 18:23:54

US3712114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1975'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:54

US3712114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:54

US3712114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:54

US3712114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1975'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:54

US3712114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:23:54

US3712114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1975'	System	28 Sep 2020 18:23:54

US3712114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1975'	System	28 Sep 2020 18:23:54

US3712114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1975'	System	28 Sep 2020 18:23:54

US3712114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1975'	System	28 Sep 2020 18:23:54

US3712114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal septum deviation, LLT: Nasal septum deviation - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:25:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:25:51
Data point term sent to Coder	System	28 Sep 2020 18:25:14
User entered 'nasal septum deviation'	(b) (4), (b) (6)	28 Sep 2020 18:24:18

US3712114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1980'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:24:18

US3712114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:24:18

US3712114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:24:18

US3712114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1980'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:24:18

US3712114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:24:18

US3712114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1980'	System	28 Sep 2020 18:24:18

US3712114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1980'	System	28 Sep 2020 18:24:18

US3712114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1980'	System	28 Sep 2020 18:24:18

US3712114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1980'	System	28 Sep 2020 18:24:18

US3712114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Skull fracture, LLT: Skull fracture - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 22:00:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 22:00:48
Data point term sent to Coder	System	28 Sep 2020 18:25:15
User entered 'left skull fracture'	(b) (4), (b) (6)	28 Sep 2020 18:25:01

US3712114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1969'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:25:01

US3712114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:25:01

US3712114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:25:01

US3712114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1969'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:25:01

US3712114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:25:01

US3712114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1969'	System	28 Sep 2020 18:25:01

US3712114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1969'	System	28 Sep 2020 18:25:01

US3712114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1969'	System	28 Sep 2020 18:25:01

US3712114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1969'	System	28 Sep 2020 18:25:01

US3712114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Skull fracture, LLT: Skull fracture - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 22:00:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 22:00:48
Data point term sent to Coder	System	28 Sep 2020 18:26:16
User entered 'left skull fracture'	(b) (4), (b) (6)	28 Sep 2020 18:25:25

US3712114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1975'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:25:25

US3712114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:25:25

US3712114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:25:25

US3712114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1975'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:25:25

US3712114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:25:25

US3712114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1975'	System	28 Sep 2020 18:25:25

US3712114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1975'	System	28 Sep 2020 18:25:25

US3712114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1975'	System	28 Sep 2020 18:25:25

US3712114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1975'	System	28 Sep 2020 18:25:25

US3712114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	28 Sep 2020 19:03:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:03:45
Data point term sent to Coder	System	28 Sep 2020 18:27:18
User entered 'basal cell carcinoma lower back'	(b) (4), (b) (6)	28 Sep 2020 18:26:20

US3712114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:26:20

US3712114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:26:20

US3712114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:26:20

US3712114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:26:20

US3712114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:26:20

US3712114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 2012'	System	28 Sep 2020 18:26:20

US3712114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '2012'	System	28 Sep 2020 18:26:20

US3712114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 2012'	System	28 Sep 2020 18:26:20

US3712114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '2012'	System	28 Sep 2020 18:26:20

US3712114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	28 Sep 2020 19:03:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:03:45
Data point term sent to Coder	System	28 Sep 2020 18:27:18
User entered 'basal cell carcinoma bilateral shoulders'	(b) (4), (b) (6)	28 Sep 2020 18:26:38

US3712114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:26:38

US3712114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:26:38

US3712114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:26:38

US3712114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:26:38

US3712114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:26:38

US3712114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 2012'	System	28 Sep 2020 18:26:38

US3712114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '2012'	System	28 Sep 2020 18:26:38

US3712114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 2012'	System	28 Sep 2020 18:26:38

US3712114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '2012'	System	28 Sep 2020 18:26:38

US3712114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Basal cell carcinoma excision - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 19:03:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 19:03:45
Data point term sent to Coder	System	28 Sep 2020 18:28:21
User entered 'basal cell carcinoma removal lower back'	(b) (4), (b) (6)	28 Sep 2020 18:27:19

US3712114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:27:19

US3712114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:27:19

US3712114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:27:19

US3712114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:27:19

US3712114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:27:19

US3712114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 2012'	System	28 Sep 2020 18:27:19

US3712114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '2012'	System	28 Sep 2020 18:27:19

US3712114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 2012'	System	28 Sep 2020 18:27:19

US3712114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '2012'	System	28 Sep 2020 18:27:19

US3712114

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Basal cell carcinoma excision - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 19:03:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 19:03:45
Data point term sent to Coder	System	28 Sep 2020 18:28:21
User entered 'basal cell carcinoma removal bilateral shoulders'	(b) (4), (b) (6)	28 Sep 2020 18:27:37

US3712114

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:27:37

US3712114

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:27:37

US3712114

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:27:37

US3712114

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:27:37

US3712114

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:27:37

US3712114

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 2012'	System	28 Sep 2020 18:27:37

US3712114

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '2012'	System	28 Sep 2020 18:27:37

US3712114

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 2012'	System	28 Sep 2020 18:27:37

US3712114

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '2012'	System	28 Sep 2020 18:27:37

US3712114

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:27:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:29:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:29:40
Data point term sent to Coder	System	28 Sep 2020 18:28:19
User entered 'hypertension'	(b) (4), (b) (6)	28 Sep 2020 18:27:52

US3712114

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1989'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:27:52

US3712114

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:27:52

US3712114

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:27:52

US3712114

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:27:52

US3712114

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:27:52

US3712114

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1989'	System	28 Sep 2020 18:27:52

US3712114

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1989'	System	28 Sep 2020 18:27:52

US3712114

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:27:52

US3712114

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:27:52

US3712114

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:29:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:29:40
Data point term sent to Coder	System	28 Sep 2020 18:28:22
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	28 Sep 2020 18:28:20

US3712114

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1989'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:28:20

US3712114

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:28:20

US3712114

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:28:20

US3712114

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:28:20

US3712114

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:28:20

US3712114

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1989'	System	28 Sep 2020 18:28:20

US3712114

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1989'	System	28 Sep 2020 18:28:20

US3712114

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:28:20

US3712114

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:28:20

US3712114

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Immune system disorders, HLGT: Immune disorders NEC, HLT: Acute and chronic sarcoidosis, PT: Sarcoidosis, LLT: Sarcoidosis - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:30:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:30:42
Data point term sent to Coder	System	28 Sep 2020 18:29:24
User entered 'sarcoidosis'	(b) (4), (b) (6)	28 Sep 2020 18:28:50

US3712114

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 2002'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:28:50

US3712114

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:28:50

US3712114

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:28:50

US3712114

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:28:50

US3712114

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:28:50

US3712114

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 2002'	System	28 Sep 2020 18:28:50

US3712114

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '2002'	System	28 Sep 2020 18:28:50

US3712114

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:28:50

US3712114

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:28:50

US3712114

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:27:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:31:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:31:45
Data point term sent to Coder	System	28 Sep 2020 18:30:25
User entered 'diabetes mellitus type 2'	(b) (4), (b) (6)	28 Sep 2020 18:29:28

US3712114

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1989'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:29:28

US3712114

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:29:28

US3712114

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:29:28

US3712114

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:29:28

US3712114

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:29:28

US3712114

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1989'	System	28 Sep 2020 18:29:28

US3712114

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1989'	System	28 Sep 2020 18:29:28

US3712114

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:29:28

US3712114

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:29:28

US3712114

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:27:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:31:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:31:44
Data point term sent to Coder	System	28 Sep 2020 18:30:25
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6)	28 Sep 2020 18:29:44

US3712114

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:29:44

US3712114

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:29:44

US3712114

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:29:44

US3712114

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:29:44

US3712114

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:29:44

US3712114

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 2000'	System	28 Sep 2020 18:29:44

US3712114

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '2000'	System	28 Sep 2020 18:29:44

US3712114

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:29:44

US3712114

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:29:44

US3712114

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 19:20:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 19:20:49
Data point term sent to Coder	System	28 Sep 2020 18:31:28
User entered 'diabetic neuropathy bilateral'	(b) (4), (b) (6)	28 Sep 2020 18:30:30

US3712114

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1989'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:30:30

US3712114

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:30:30

US3712114

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:30:30

US3712114

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:30:30

US3712114

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:30:30

US3712114

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1989'	System	28 Sep 2020 18:30:30

US3712114

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1989'	System	28 Sep 2020 18:30:30

US3712114

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:30:30

US3712114

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	28 Sep 2020 18:30:30

US3712114

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Vascular disorders, HLT: Vascular haemorrhagic disorders, HLT: Haemorrhages NEC, PT: Haematoma, LLT: Hematoma - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 19:34:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 19:34:44
Data point term sent to Coder	System	28 Sep 2020 18:31:26
User entered 'hematoma left ankle'	(b) (4), (b) (6)	28 Sep 2020 18:31:08

US3712114

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1973'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:08

US3712114

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:08

US3712114

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:08

US3712114

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1973'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:08

US3712114

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:08

US3712114

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1973'	System	28 Sep 2020 18:31:08

US3712114

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1973'	System	28 Sep 2020 18:31:08

US3712114

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1973'	System	28 Sep 2020 18:31:08

US3712114

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1973'	System	28 Sep 2020 18:31:08

US3712114

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Vascular therapeutic procedures NEC, PT: Haematoma evacuation, LLT: Hematoma evacuation - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 10:12:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 10:12:49
Data point term sent to Coder	System	28 Sep 2020 18:31:29
User entered 'hematoma left ankle removed'	(b) (4), (b) (6)	28 Sep 2020 18:31:23

US3712114

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1973'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:23

US3712114

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:23

US3712114

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:23

US3712114

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 1973'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:23

US3712114

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:23

US3712114

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1973'	System	28 Sep 2020 18:31:23

US3712114

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1973'	System	28 Sep 2020 18:31:23

US3712114

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 1973'	System	28 Sep 2020 18:31:23

US3712114

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '1973'	System	28 Sep 2020 18:31:23

US3712114

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:27:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Elbow fracture - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:33:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:33:48
Data point term sent to Coder	System	28 Sep 2020 18:32:30
User entered 'left elbow fracture'	(b) (4), (b) (6)	28 Sep 2020 18:31:39

US3712114

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:39

US3712114

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:39

US3712114

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:39

US3712114

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:39

US3712114

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:39

US3712114

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 2018'	System	28 Sep 2020 18:31:39

US3712114

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '2018'	System	28 Sep 2020 18:31:39

US3712114

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 2018'	System	28 Sep 2020 18:31:39

US3712114

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '2018'	System	28 Sep 2020 18:31:39

US3712114

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:27:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Elbow operation, LLT: Elbow operation - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 21:55:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 21:55:45
Data point term sent to Coder	System	28 Sep 2020 18:32:29
User entered 'left elbow surgical repair'	(b) (4), (b) (6)	28 Sep 2020 18:31:57

US3712114

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:57

US3712114

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:57

US3712114

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:57

US3712114

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:57

US3712114

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:31:57

US3712114

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 2018'	System	28 Sep 2020 18:31:57

US3712114

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '2018'	System	28 Sep 2020 18:31:57

US3712114

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 2018'	System	28 Sep 2020 18:31:57

US3712114

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '2018'	System	28 Sep 2020 18:31:57

US3712114

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:27:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 14:59:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 14:59:33
Data point term sent to Coder	System	11 Nov 2020 14:58:07
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 14:57:25
Data point term sent to Coder	System	11 Nov 2020 14:39:42
User entered 'congestion'	(b) (4), (b) (6)	11 Nov 2020 14:39:40

US3712114

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:39:40

US3712114

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:39:40

US3712114

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:39:40

US3712114

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:39:40

US3712114

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:39:40

US3712114

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jan 2019'	System	11 Nov 2020 14:39:40

US3712114

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '2019'	System	11 Nov 2020 14:39:40

US3712114

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	11 Nov 2020 14:39:40

US3712114

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	11 Nov 2020 14:39:40

US3712114

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
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)	21 Apr 2021 15:11:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 15:11:03
Data point term sent to Coder	System	21 Apr 2021 14:46:40
User entered 'prostate cancer'	(b) (4), (b) (6)	21 Apr 2021 14:46:11

US3712114

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	(b) (4)	21 Apr 2021 14:46:32
User entered '14 Jul 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 14:46:32
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	21 Apr 2021 14:46:11
User entered '14 Jan 2021'	(b) (4), (b) (6)	21 Apr 2021 14:46:11

US3712114

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:46:11

US3712114

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:46:11

US3712114

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:46:11

US3712114

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:46:11

US3712114

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'Jul 2020'	System	21 Apr 2021 14:46:32
User entered 'Jan 2021'	System	21 Apr 2021 14:46:11

US3712114

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '2020'	System	21 Apr 2021 14:46:32
User entered '2021'	System	21 Apr 2021 14:46:11

US3712114

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	21 Apr 2021 14:46:11

US3712114

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered empty.	System	21 Apr 2021 14:46:11

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:17:50

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:17:50

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Sep 2020 18:19:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Sep 2020 18:19:02
User entered '10:40' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:19:02
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 18:17:50
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:17:50

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '16 Sep 2020 10:40'	System	28 Sep 2020 18:19:02
User entered empty.	System	28 Sep 2020 18:17:50

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '174.0' cm	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:17:50
DataPoint set to visible.	System	24 Sep 2020 15:52:32

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '95.3' kg	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:17:50
DataPoint set to visible.	System	24 Sep 2020 15:52:32

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered '31.47708'	System	28 Sep 2020 18:17:50
DataPoint set to visible.	System	24 Sep 2020 15:52:32

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'kg/m2'	System	28 Sep 2020 18:17:50
DataPoint set to visible.	System	24 Sep 2020 15:52:32

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Sep 2020 18:19:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Sep 2020 18:19:02
User entered '36.9' C reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:19:02
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 18:17:50
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:17:50

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:19:02
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:17:50

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:17:50

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Sep 2020 18:19:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Sep 2020 18:19:02
User entered '65' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:19:02
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 18:17:50
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:17:50

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'bpm'	System	28 Sep 2020 18:19:02
User entered empty.	System	28 Sep 2020 18:17:50

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Sep 2020 18:19:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Sep 2020 18:19:02
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:19:02
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 18:17:50
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:17:50

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'breaths/min'	System	28 Sep 2020 18:19:02
User entered empty.	System	28 Sep 2020 18:17:50

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Sep 2020 18:19:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Sep 2020 18:19:02
User entered '123' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:19:02
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 18:17:50
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:17:50

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'mmHg'	System	28 Sep 2020 18:19:02
User entered empty.	System	28 Sep 2020 18:17:50

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	28 Sep 2020 18:19:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Sep 2020 18:19:02
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:19:02
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 18:17:50
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:17:50

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User entered 'mmHg'	System	28 Sep 2020 18:19:02
User entered empty.	System	28 Sep 2020 18:17:50

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50

US3712114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50

US3712114

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:19:07

US3712114

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:19:07

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

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)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

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)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

[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)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

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)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

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)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

[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)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

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)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

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)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Place of worship, church.'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'I'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

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)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

[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)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

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)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:55:50
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:20:28

US3712114

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:52:49

US3712114

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:52:49

US3712114

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:52:49

US3712114

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'VISIT1'	System	24 Sep 2020 15:52:49

US3712114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '24 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 14:24:42

US3712114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:27:55

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '191284'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 14:24:42

US3712114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:27:55

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 14:24:42

US3712114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:27:55

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:54:47

US3712114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:27:55

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:54:47

US3712114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:27:55

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:54:47

US3712114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:27:55

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:54:47

US3712114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:27:55

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:54:47

US3712114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:27:55

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:54:47
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:19:35

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '173.0' cm	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '96.6' kg	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '173.0' cm	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '96.6' kg	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '09:20'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered '24 Sep 2020 09:20'	System	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '77'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'bpm'	System	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '16'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'breaths/min'	System	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '122'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'mmHg'	System	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '73'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'mmHg'	System	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '173.0' cm	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '96.6' kg	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '12:10'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered '24 Sep 2020 12:10'	System	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '69'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'bpm'	System	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '16'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'breaths/min'	System	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '122'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'mmHg'	System	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '68'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'mmHg'	System	28 Sep 2020 18:50:58

US3712114

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:51:04

US3712114

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:51:04

US3712114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:55:18

US3712114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:55:18

US3712114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:55:18

US3712114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 15:55:18

US3712114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:55:18

US3712114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '11:40'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:55:18

US3712114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User entered '24 Sep 2020 11:40'	System	24 Sep 2020 15:55:18

US3712114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:55:18

US3712114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User entered 'ONCE'	System	24 Sep 2020 15:55:18

US3712114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 15:55:18

US3712114

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:51:21

US3712114

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:51:21

US3712114

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '09:30'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:51:21

US3712114

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User entered '24 Sep 2020 09:30'	System	28 Sep 2020 18:51:21

US3712114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:27:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:51:33

US3712114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:27:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	28 Sep 2020 18:51:33

US3712114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:51:33

US3712114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:27:55

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '09:35'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:51:33

US3712114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:27:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User entered '24 Sep 2020 09:35'	System	28 Sep 2020 18:51:33

US3712114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:27:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	28 Sep 2020 18:51:33

US3712114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 21:08:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 21:08:43
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:51:33

US3712114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:27:55

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 21:08:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 21:08:43
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '09:35'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:51:33

US3712114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:27:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User entered empty.	System	15 Feb 2021 21:08:43
User entered '24 Sep 2020 09:35'	System	28 Sep 2020 18:51:33

US3712114

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:55:29

US3712114

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User entered 'I'	System	24 Sep 2020 15:55:29

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T12:11:42', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '82ca680c-f985-4d17-86de-24e45a6bcb97'	System	24 Sep 2020 16:12:18
User entered 'Yes (Y)'	System	24 Sep 2020 16:12:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T12:11:51', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '82ca680c-f985-4d17-86de-24e45a6bcb97' User entered '98.4'	System	24 Sep 2020 16:12:18
	System	24 Sep 2020 16:12:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T12:12:07', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '82ca680c-f985-4d17-86de-24e45a6bcb97'	System	24 Sep 2020 16:12:18
User entered 'No (N)'	System	24 Sep 2020 16:12:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T12:12:14', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '82ca680c-f985-4d17-86de-24e45a6bcb97'	System	24 Sep 2020 16:12:18
User entered '24 Sep 2020 12:12'	System	24 Sep 2020 16:12:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '24 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '24 Sep 2020 14:30'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T20:23:42', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '830bb129-af4a-4e2b-9f4c-a7e45d2110b9' User entered 'Yes (Y)'	System	25 Sep 2020 00:26:09
	System	25 Sep 2020 00:26:09

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T20:25:46', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '830bb129-af4a-4e2b-9f4c-a7e45d2110b9' User entered '95.8'	System	25 Sep 2020 00:26:09
	System	25 Sep 2020 00:26:09

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T20:25:51', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '830bb129-af4a-4e2b-9f4c-a7e45d2110b9'	System	25 Sep 2020 00:26:09
User entered 'No (N)'	System	25 Sep 2020 00:26:09

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T20:26:01', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '830bb129-af4a-4e2b-9f4c-a7e45d2110b9'	System	25 Sep 2020 00:26:09
User entered '24 Sep 2020 20:26'	System	25 Sep 2020 00:26:09

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '24 Sep 2020 15:25'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 2'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-25T22:35:54', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '5a236a8e-3fda-4be6-80b4-c16ffbf42353' User entered 'Yes (Y)'	System	26 Sep 2020 02:36:35
	System	26 Sep 2020 02:36:35

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-25T22:36:21', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '5a236a8e-3fda-4be6-80b4-c16ffbf42353' User entered '96.1'	System	26 Sep 2020 02:36:35
	System	26 Sep 2020 02:36:35

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-25T22:36:27', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '5a236a8e-3fda-4be6-80b4-c16ffbf42353'	System	26 Sep 2020 02:36:35
User entered 'No (N)'	System	26 Sep 2020 02:36:35

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-25T22:36:32', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '5a236a8e-3fda-4be6-80b4-c16ffbf42353' User entered '25 Sep 2020 22:36'	System	26 Sep 2020 02:36:35
	System	26 Sep 2020 02:36:35

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 3'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-26T23:44:27', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fa70c895-237a-420d-a324-46892f66d1a5'	System	27 Sep 2020 03:44:48
User entered 'Yes (Y)'	System	27 Sep 2020 03:44:48

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-26T23:44:37', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fa70c895-237a-420d-a324-46892f66d1a5' User entered '97.1'	System	27 Sep 2020 03:44:48
	System	27 Sep 2020 03:44:48

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-26T23:44:41', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fa70c895-237a-420d-a324-46892f66d1a5'	System	27 Sep 2020 03:44:48
User entered 'No (N)'	System	27 Sep 2020 03:44:48

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-26T23:44:46', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fa70c895-237a-420d-a324-46892f66d1a5'	System	27 Sep 2020 03:44:48
User entered '26 Sep 2020 23:44'	System	27 Sep 2020 03:44:48

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 4'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-27T22:05:33', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '1777268a-add3-4412-8d80-dba7e696650d' User entered 'Yes (Y)'	System	28 Sep 2020 02:06:17
	System	28 Sep 2020 02:06:17

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-27T22:05:58', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '1777268a-add3-4412-8d80-dba7e696650d' User entered '97.0'	System	28 Sep 2020 02:06:17
	System	28 Sep 2020 02:06:17

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-27T22:06:03', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '1777268a-add3-4412-8d80-dba7e696650d' User entered 'No (N)'	System	28 Sep 2020 02:06:17
	System	28 Sep 2020 02:06:17

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-27T22:06:10', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '1777268a-add3-4412-8d80-dba7e696650d' User entered '27 Sep 2020 22:06'	System	28 Sep 2020 02:06:17
	System	28 Sep 2020 02:06:17

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 5'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-29T00:00:12', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '9a88f997-ec7c-44fd-8c22-a6c186ac155d'	System	29 Sep 2020 04:01:12
User entered 'Yes (Y)'	System	29 Sep 2020 04:01:12

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-29T00:01:02', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '9a88f997-ec7c-44fd-8c22-a6c186ac155d' User entered '97.1'	System	29 Sep 2020 04:01:12
	System	29 Sep 2020 04:01:12

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-29T00:01:06', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '9a88f997-ec7c-44fd-8c22-a6c186ac155d'	System	29 Sep 2020 04:01:12
User entered 'No (N)'	System	29 Sep 2020 04:01:12

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-29T00:01:10', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '9a88f997-ec7c-44fd-8c22-a6c186ac155d' User entered '29 Sep 2020 00:01'	System	29 Sep 2020 04:01:12
	System	29 Sep 2020 04:01:12

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 6'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:27:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T00:00:20', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '68469d96-4dff-4420-ba31-55a8f9203f13' User entered 'Yes (Y)'	System	30 Sep 2020 04:01:09
	System	30 Sep 2020 04:01:09

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T00:00:51', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '68469d96-4dff-4420-ba31-55a8f9203f13' User entered '96.9'	System	30 Sep 2020 04:01:09
	System	30 Sep 2020 04:01:09

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T00:00:54', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '68469d96-4dff-4420-ba31-55a8f9203f13'	System	30 Sep 2020 04:01:09
User entered 'No (N)'	System	30 Sep 2020 04:01:09

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T00:00:58', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '68469d96-4dff-4420-ba31-55a8f9203f13' User entered '30 Sep 2020 00:00'	System	30 Sep 2020 04:01:09
	System	30 Sep 2020 04:01:09

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 7'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T21:43:38', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '05fe6061-336f-4941-8121-50d9aebacc58' User entered 'Yes (Y)'	System	01 Oct 2020 01:44:03
	System	01 Oct 2020 01:44:03

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T21:43:48', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '05fe6061-336f-4941-8121-50d9aebacc58' User entered '97.7'	System	01 Oct 2020 01:44:03
	System	01 Oct 2020 01:44:03

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T21:43:52', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '05fe6061-336f-4941-8121-50d9aebacc58' User entered 'No (N)'	System	01 Oct 2020 01:44:03
	System	01 Oct 2020 01:44:03

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T21:43:59', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '05fe6061-336f-4941-8121-50d9aebacc58' User entered '30 Sep 2020 21:43'	System	01 Oct 2020 01:44:03
	System	01 Oct 2020 01:44:03

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T12:12:58', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '025a1c95-bc72-4e67-a329-1e1e8465fb69'	System	24 Sep 2020 16:13:18
User entered 'None (1)'	System	24 Sep 2020 16:13:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T12:13:01', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '025a1c95-bc72-4e67-a329-1e1e8465fb69' User entered 'No (N)'	System	24 Sep 2020 16:13:18
	System	24 Sep 2020 16:13:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T12:13:04', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '025a1c95-bc72-4e67-a329-1e1e8465fb69' User entered 'No (N)'	System	24 Sep 2020 16:13:18
	System	24 Sep 2020 16:13:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T12:13:10', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '025a1c95-bc72-4e67-a329-1e1e8465fb69'	System	24 Sep 2020 16:13:18
User entered 'None (1)'	System	24 Sep 2020 16:13:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T12:13:15', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '025a1c95-bc72-4e67-a329-1e1e8465fb69' User entered '24 Sep 2020 12:13'	System	24 Sep 2020 16:13:18
	System	24 Sep 2020 16:13:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '24 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '24 Sep 2020 14:30'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T20:26:14', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c125d950-99b6-4dd8-a3c3-9956144b3315'	System	25 Sep 2020 00:27:18
User entered 'None (1)'	System	25 Sep 2020 00:27:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T20:26:59', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c125d950-99b6-4dd8-a3c3-9956144b3315'	System	25 Sep 2020 00:27:18
User entered 'No (N)'	System	25 Sep 2020 00:27:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T20:27:02', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c125d950-99b6-4dd8-a3c3-9956144b3315'	System	25 Sep 2020 00:27:18
User entered 'No (N)'	System	25 Sep 2020 00:27:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T20:27:09', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c125d950-99b6-4dd8-a3c3-9956144b3315'	System	25 Sep 2020 00:27:18
User entered 'None (1)'	System	25 Sep 2020 00:27:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T20:27:14', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c125d950-99b6-4dd8-a3c3-9956144b3315'	System	25 Sep 2020 00:27:18
User entered '24 Sep 2020 20:27'	System	25 Sep 2020 00:27:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '24 Sep 2020 15:25'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 2'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-25T22:37:39', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '1ca073fc-55c3-437b-825a-af5c1de9adde' User entered 'None (1)'	System	26 Sep 2020 02:39:45
	System	26 Sep 2020 02:39:45

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-25T22:39:23', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '1ca073fc-55c3-437b-825a-af5c1de9adde' User entered 'No (N)'	System	26 Sep 2020 02:39:45
	System	26 Sep 2020 02:39:45

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-25T22:39:30', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '1ca073fc-55c3-437b-825a-af5c1de9adde' User entered 'No (N)'	System	26 Sep 2020 02:39:45
	System	26 Sep 2020 02:39:45

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-25T22:39:37', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '1ca073fc-55c3-437b-825a-af5c1de9adde' User entered 'None (1)'	System	26 Sep 2020 02:39:45
	System	26 Sep 2020 02:39:45

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-25T22:39:40', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '1ca073fc-55c3-437b-825a-af5c1de9adde' User entered '25 Sep 2020 22:39'	System	26 Sep 2020 02:39:45
	System	26 Sep 2020 02:39:45

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 3'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-26T23:44:51', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c17e5c99-991d-4df3-af5e-cab63c7a1655'	System	27 Sep 2020 03:45:11
User entered 'None (1)'	System	27 Sep 2020 03:45:11

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-26T23:44:55', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c17e5c99-991d-4df3-af5e-cab63c7a1655'	System	27 Sep 2020 03:45:11
User entered 'No (N)'	System	27 Sep 2020 03:45:11

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-26T23:44:58', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c17e5c99-991d-4df3-af5e-cab63c7a1655'	System	27 Sep 2020 03:45:11
User entered 'No (N)'	System	27 Sep 2020 03:45:11

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-26T23:45:04', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c17e5c99-991d-4df3-af5e-cab63c7a1655'	System	27 Sep 2020 03:45:11
User entered 'None (1)'	System	27 Sep 2020 03:45:11

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-26T23:45:06', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c17e5c99-991d-4df3-af5e-cab63c7a1655'	System	27 Sep 2020 03:45:11
User entered '26 Sep 2020 23:45'	System	27 Sep 2020 03:45:11

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 4'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-27T22:06:17', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '8f5e6ba2-2240-4d13-98b0-79b1bdf3de37'	System	28 Sep 2020 02:06:36
User entered 'None (1)'	System	28 Sep 2020 02:06:36

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-27T22:06:20', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '8f5e6ba2-2240-4d13-98b0-79b1bdf3de37'	System	28 Sep 2020 02:06:36
User entered 'No (N)'	System	28 Sep 2020 02:06:36

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-27T22:06:24', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '8f5e6ba2-2240-4d13-98b0-79b1bdf3de37'	System	28 Sep 2020 02:06:36
User entered 'No (N)'	System	28 Sep 2020 02:06:36

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-27T22:06:29', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '8f5e6ba2-2240-4d13-98b0-79b1bdf3de37'	System	28 Sep 2020 02:06:36
User entered 'None (1)'	System	28 Sep 2020 02:06:36

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-27T22:06:32', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '8f5e6ba2-2240-4d13-98b0-79b1bdf3de37'	System	28 Sep 2020 02:06:36
User entered '27 Sep 2020 22:06'	System	28 Sep 2020 02:06:36

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 5'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-29T00:01:22', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '0d6d4fac-bd62-4bb9-8fe1-7642ebfea447'	System	29 Sep 2020 04:01:38
User entered 'None (1)'	System	29 Sep 2020 04:01:38

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-29T00:01:25', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '0d6d4fac-bd62-4bb9-8fe1-7642ebfea447'	System	29 Sep 2020 04:01:38
User entered 'No (N)'	System	29 Sep 2020 04:01:38

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-29T00:01:28', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '0d6d4fac-bd62-4bb9-8fe1-7642ebfea447'	System	29 Sep 2020 04:01:38
User entered 'No (N)'	System	29 Sep 2020 04:01:38

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-29T00:01:30', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '0d6d4fac-bd62-4bb9-8fe1-7642ebfea447'	System	29 Sep 2020 04:01:38
User entered 'None (1)'	System	29 Sep 2020 04:01:38

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-29T00:01:33', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '0d6d4fac-bd62-4bb9-8fe1-7642ebfea447'	System	29 Sep 2020 04:01:38
User entered '29 Sep 2020 00:01'	System	29 Sep 2020 04:01:38

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 6'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T00:01:03', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '5d38452c-11f1-438a-8436-6d49a4b560ff' User entered 'None (1)'	System	30 Sep 2020 04:01:23
	System	30 Sep 2020 04:01:23

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T00:01:06', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '5d38452c-11f1-438a-8436-6d49a4b560ff' User entered 'No (N)'	System	30 Sep 2020 04:01:23
	System	30 Sep 2020 04:01:23

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T00:01:09', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '5d38452c-11f1-438a-8436-6d49a4b560ff' User entered 'No (N)'	System	30 Sep 2020 04:01:23
	System	30 Sep 2020 04:01:23

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T00:01:12', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '5d38452c-11f1-438a-8436-6d49a4b560ff' User entered 'None (1)'	System	30 Sep 2020 04:01:23
	System	30 Sep 2020 04:01:23

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T00:01:15', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '5d38452c-11f1-438a-8436-6d49a4b560ff' User entered '30 Sep 2020 00:01'	System	30 Sep 2020 04:01:23
	System	30 Sep 2020 04:01:23

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 7'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T21:44:05', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '858d4141-3216-4107-9be2-2530ca59148b'	System	01 Oct 2020 01:44:23
User entered 'None (1)'	System	01 Oct 2020 01:44:23

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T21:44:09', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '858d4141-3216-4107-9be2-2530ca59148b' User entered 'No (N)'	System	01 Oct 2020 01:44:23
	System	01 Oct 2020 01:44:23

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T21:44:13', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '858d4141-3216-4107-9be2-2530ca59148b' User entered 'No (N)'	System	01 Oct 2020 01:44:23
	System	01 Oct 2020 01:44:23

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T21:44:16', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '858d4141-3216-4107-9be2-2530ca59148b'	System	01 Oct 2020 01:44:23
User entered 'None (1)'	System	01 Oct 2020 01:44:23

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T21:44:19', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '858d4141-3216-4107-9be2-2530ca59148b' User entered '30 Sep 2020 21:44'	System	01 Oct 2020 01:44:23
	System	01 Oct 2020 01:44:23

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T12:13:27', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '665980ee-a204-41a1-8e7a-51e413b2e7a7' User entered 'None (0)'	System	24 Sep 2020 16:14:12
	System	24 Sep 2020 16:14:12

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T12:13:33', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '665980ee-a204-41a1-8e7a-51e413b2e7a7' User entered 'None (0)'	System	24 Sep 2020 16:14:12
	System	24 Sep 2020 16:14:12

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T12:13:38', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '665980ee-a204-41a1-8e7a-51e413b2e7a7' User entered 'None (0)'	System	24 Sep 2020 16:14:12
	System	24 Sep 2020 16:14:12

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T12:13:41', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '665980ee-a204-41a1-8e7a-51e413b2e7a7' User entered 'None (0)'	System	24 Sep 2020 16:14:12
	System	24 Sep 2020 16:14:12

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T12:13:46', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '665980ee-a204-41a1-8e7a-51e413b2e7a7' User entered 'None (0)'	System	24 Sep 2020 16:14:12
	System	24 Sep 2020 16:14:12

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T12:13:48', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '665980ee-a204-41a1-8e7a-51e413b2e7a7' User entered 'None (0)'	System	24 Sep 2020 16:14:12
	System	24 Sep 2020 16:14:12

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T12:14:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '665980ee-a204-41a1-8e7a-51e413b2e7a7' User entered 'No (N)'	System	24 Sep 2020 16:14:12
	System	24 Sep 2020 16:14:12

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T12:14:07', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '665980ee-a204-41a1-8e7a-51e413b2e7a7' User entered '24 Sep 2020 12:14'	System	24 Sep 2020 16:14:12
	System	24 Sep 2020 16:14:12

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '24 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '24 Sep 2020 14:30'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T20:27:22', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '4053d966-662e-499a-881c-a148b03292a1' User entered 'None (0)'	System	25 Sep 2020 00:27:59
	System	25 Sep 2020 00:27:59

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T20:27:27', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '4053d966-662e-499a-881c-a148b03292a1' User entered 'None (0)'	System	25 Sep 2020 00:27:59
	System	25 Sep 2020 00:27:59

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T20:27:30', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '4053d966-662e-499a-881c-a148b03292a1' User entered 'None (0)'	System	25 Sep 2020 00:27:59
	System	25 Sep 2020 00:27:59

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T20:27:33', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '4053d966-662e-499a-881c-a148b03292a1' User entered 'None (0)'	System	25 Sep 2020 00:27:59
	System	25 Sep 2020 00:27:59

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T20:27:36', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '4053d966-662e-499a-881c-a148b03292a1' User entered 'None (0)'	System	25 Sep 2020 00:27:59
	System	25 Sep 2020 00:27:59

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T20:27:48', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '4053d966-662e-499a-881c-a148b03292a1' User entered 'None (0)'	System	25 Sep 2020 00:27:59
	System	25 Sep 2020 00:27:59

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T20:27:52', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '4053d966-662e-499a-881c-a148b03292a1' User entered 'No (N)'	System	25 Sep 2020 00:27:59
	System	25 Sep 2020 00:27:59

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-24T20:27:55', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '4053d966-662e-499a-881c-a148b03292a1' User entered '24 Sep 2020 20:27'	System	25 Sep 2020 00:27:59
	System	25 Sep 2020 00:27:59

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '24 Sep 2020 15:25'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 2'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-25T22:40:20', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2ad510e7-1077-4e28-a826-a6d61e0959ae' User entered 'None (0)'	System	26 Sep 2020 02:41:04
	System	26 Sep 2020 02:41:04

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-25T22:40:23', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2ad510e7-1077-4e28-a826-a6d61e0959ae' User entered 'None (0)'	System	26 Sep 2020 02:41:04
	System	26 Sep 2020 02:41:04

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-25T22:40:26', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2ad510e7-1077-4e28-a826-a6d61e0959ae' User entered 'None (0)'	System	26 Sep 2020 02:41:04
	System	26 Sep 2020 02:41:04

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-25T22:40:29', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2ad510e7-1077-4e28-a826-a6d61e0959ae' User entered 'None (0)'	System	26 Sep 2020 02:41:04
	System	26 Sep 2020 02:41:04

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-25T22:40:40', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2ad510e7-1077-4e28-a826-a6d61e0959ae' User entered 'None (0)'	System	26 Sep 2020 02:41:04
	System	26 Sep 2020 02:41:04

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-25T22:40:44', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2ad510e7-1077-4e28-a826-a6d61e0959ae' User entered 'None (0)'	System	26 Sep 2020 02:41:04
	System	26 Sep 2020 02:41:04

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-25T22:40:56', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2ad510e7-1077-4e28-a826-a6d61e0959ae' User entered 'No (N)'	System	26 Sep 2020 02:41:04
	System	26 Sep 2020 02:41:04

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-25T22:41:01', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2ad510e7-1077-4e28-a826-a6d61e0959ae' User entered '25 Sep 2020 22:41'	System	26 Sep 2020 02:41:04
	System	26 Sep 2020 02:41:04

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 3'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-26T23:45:15', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '99b63d9b-e920-46ee-a2ed-6dd084bf8ab9' User entered 'None (0)'	System	27 Sep 2020 03:45:46
	System	27 Sep 2020 03:45:46

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-26T23:45:18', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '99b63d9b-e920-46ee-a2ed-6dd084bf8ab9' User entered 'None (0)'	System	27 Sep 2020 03:45:46
	System	27 Sep 2020 03:45:46

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-26T23:45:22', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '99b63d9b-e920-46ee-a2ed-6dd084bf8ab9' User entered 'None (0)'	System	27 Sep 2020 03:45:46
	System	27 Sep 2020 03:45:46

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-26T23:45:25', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '99b63d9b-e920-46ee-a2ed-6dd084bf8ab9' User entered 'None (0)'	System	27 Sep 2020 03:45:46
	System	27 Sep 2020 03:45:46

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-26T23:45:31', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '99b63d9b-e920-46ee-a2ed-6dd084bf8ab9' User entered 'None (0)'	System	27 Sep 2020 03:45:46
	System	27 Sep 2020 03:45:46

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-26T23:45:34', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '99b63d9b-e920-46ee-a2ed-6dd084bf8ab9' User entered 'None (0)'	System	27 Sep 2020 03:45:46
	System	27 Sep 2020 03:45:46

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-26T23:45:40', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '99b63d9b-e920-46ee-a2ed-6dd084bf8ab9' User entered 'No (N)'	System	27 Sep 2020 03:45:46
	System	27 Sep 2020 03:45:46

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-26T23:45:43', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '99b63d9b-e920-46ee-a2ed-6dd084bf8ab9' User entered '26 Sep 2020 23:45'	System	27 Sep 2020 03:45:46
	System	27 Sep 2020 03:45:46

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 4'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-27T22:06:40', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'a8b9e390-c6b4-4a8b-8ca2-64baf6a057a' User entered 'None (0)'	System	28 Sep 2020 02:07:19
	System	28 Sep 2020 02:07:19

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-27T22:06:45', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'a8b9e390-c6b4-4a8b-8ca2-64baf6a057a' User entered 'None (0)'	System	28 Sep 2020 02:07:19
	System	28 Sep 2020 02:07:19

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-27T22:06:48', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'a8b9e390-c6b4-4a8b-8ca2-64baf6a057a' User entered 'None (0)'	System	28 Sep 2020 02:07:19
	System	28 Sep 2020 02:07:19

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-27T22:06:56', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'a8b9e390-c6b4-4a8b-8ca2-64baf6a057a' User entered 'None (0)'	System	28 Sep 2020 02:07:19
	System	28 Sep 2020 02:07:19

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-27T22:06:59', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'a8b9e390-c6b4-4a8b-8ca2-64baf6a057a' User entered 'None (0)'	System	28 Sep 2020 02:07:19
	System	28 Sep 2020 02:07:19

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-27T22:07:02', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'a8b9e390-c6b4-4a8b-8ca2-64baf6a057a' User entered 'None (0)'	System	28 Sep 2020 02:07:19
	System	28 Sep 2020 02:07:19

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-27T22:07:06', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'a8b9e390-c6b4-4a8b-8ca2-64baf6a057a' User entered 'No (N)'	System	28 Sep 2020 02:07:19
	System	28 Sep 2020 02:07:19

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-27T22:07:12', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'a8b9e390-c6b4-4a8b-8ca2-64baf6a057a' User entered '27 Sep 2020 22:07'	System	28 Sep 2020 02:07:19
	System	28 Sep 2020 02:07:19

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 5'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-29T00:01:37', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '42bcc92e-c2da-4020-9f22-e243eeeeaa519' User entered 'None (0)'	System	29 Sep 2020 04:02:07
	System	29 Sep 2020 04:02:07

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-29T00:01:40', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '42bcc92e-c2da-4020-9f22-e243eeeeaa519' User entered 'None (0)'	System	29 Sep 2020 04:02:07
	System	29 Sep 2020 04:02:07

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-29T00:01:44', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '42bcc92e-c2da-4020-9f22-e243eeeeaa519' User entered 'None (0)'	System	29 Sep 2020 04:02:07
	System	29 Sep 2020 04:02:07

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-29T00:01:47', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '42bcc92e-c2da-4020-9f22-e243eeeeaa519' User entered 'None (0)'	System	29 Sep 2020 04:02:07
	System	29 Sep 2020 04:02:07

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-29T00:01:49', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '42bcc92e-c2da-4020-9f22-e243eeaa519' User entered 'None (0)'	System	29 Sep 2020 04:02:07
	System	29 Sep 2020 04:02:07

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-29T00:01:53', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '42bcc92e-c2da-4020-9f22-e243eeeeaa519' User entered 'None (0)'	System	29 Sep 2020 04:02:07
	System	29 Sep 2020 04:02:07

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-29T00:01:58', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '42bcc92e-c2da-4020-9f22-e243eeeeaa519' User entered 'No (N)'	System	29 Sep 2020 04:02:07
	System	29 Sep 2020 04:02:07

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-29T00:02:01', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '42bcc92e-c2da-4020-9f22-e243eeaaa519' User entered '29 Sep 2020 00:02'	System	29 Sep 2020 04:02:07
	System	29 Sep 2020 04:02:07

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 6'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T00:01:20', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e558ee6c-9fbd-49e3-8cce-7d2ebf035df2' User entered 'None (0)'	System	30 Sep 2020 04:01:43
	System	30 Sep 2020 04:01:43

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T00:01:23', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e558ee6c-9fbd-49e3-8cce-7d2ebf035df2' User entered 'None (0)'	System	30 Sep 2020 04:01:43
	System	30 Sep 2020 04:01:43

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T00:01:26', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e558ee6c-9fbd-49e3-8cce-7d2ebf035df2' User entered 'None (0)'	System	30 Sep 2020 04:01:43
	System	30 Sep 2020 04:01:43

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T00:01:28', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e558ee6c-9fbd-49e3-8cce-7d2ebf035df2' User entered 'None (0)'	System	30 Sep 2020 04:01:43
	System	30 Sep 2020 04:01:43

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T00:01:31', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e558ee6c-9fbd-49e3-8cce-7d2ebf035df2' User entered 'None (0)'	System	30 Sep 2020 04:01:43
	System	30 Sep 2020 04:01:43

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T00:01:33', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e558ee6c-9fbd-49e3-8cce-7d2ebf035df2' User entered 'None (0)'	System	30 Sep 2020 04:01:43
	System	30 Sep 2020 04:01:43

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T00:01:37', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e558ee6c-9fbd-49e3-8cce-7d2ebf035df2'	System	30 Sep 2020 04:01:43
User entered 'No (N)'	System	30 Sep 2020 04:01:43

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T00:01:40', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e558ee6c-9fbd-49e3-8cce-7d2ebf035df2' User entered '30 Sep 2020 00:01'	System	30 Sep 2020 04:01:43
	System	30 Sep 2020 04:01:43

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	24 Sep 2020 15:55:18
User entered 'Day 7'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T21:44:25', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '80d4bca3-1bdd-407d-bf7f-c7b5005d421b' User entered 'None (0)'	System	01 Oct 2020 01:44:53
	System	01 Oct 2020 01:44:53

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T21:44:28', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '80d4bca3-1bdd-407d-bf7f-c7b5005d421b' User entered 'None (0)'	System	01 Oct 2020 01:44:53
	System	01 Oct 2020 01:44:53

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T21:44:30', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '80d4bca3-1bdd-407d-bf7f-c7b5005d421b' User entered 'None (0)'	System	01 Oct 2020 01:44:53
	System	01 Oct 2020 01:44:53

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T21:44:33', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '80d4bca3-1bdd-407d-bf7f-c7b5005d421b' User entered 'None (0)'	System	01 Oct 2020 01:44:53
	System	01 Oct 2020 01:44:53

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T21:44:36', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '80d4bca3-1bdd-407d-bf7f-c7b5005d421b' User entered 'None (0)'	System	01 Oct 2020 01:44:53
	System	01 Oct 2020 01:44:53

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T21:44:39', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '80d4bca3-1bdd-407d-bf7f-c7b5005d421b' User entered 'None (0)'	System	01 Oct 2020 01:44:53
	System	01 Oct 2020 01:44:53

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T21:44:45', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '80d4bca3-1bdd-407d-bf7f-c7b5005d421b' User entered 'No (N)'	System	01 Oct 2020 01:44:53
	System	01 Oct 2020 01:44:53

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-09-30T21:44:49', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '80d4bca3-1bdd-407d-bf7f-c7b5005d421b' User entered '30 Sep 2020 21:44'	System	01 Oct 2020 01:44:53
	System	01 Oct 2020 01:44:53

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 15:55:18

US3712114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 15:55:18

US3712114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:15:16

US3712114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:15:16

US3712114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:15:16

US3712114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:15:16

US3712114

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:15:54

US3712114

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User entered 'I'	System	05 Oct 2020 19:15:54

US3712114

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:10:18

US3712114

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '08 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:10:18

US3712114

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:10:18

US3712114

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:10:18

US3712114

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:10:25

US3712114

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User entered 'I'	System	13 Oct 2020 13:10:25

US3712114

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:31:53

US3712114

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:31:53

US3712114

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:31:53

US3712114

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:31:53

US3712114

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:53:08

US3712114

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User entered 'I'	System	22 Oct 2020 14:53:08

US3712114

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:53:21

US3712114

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:53:21

US3712114

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:53:21

US3712114

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'VISIT2'	System	22 Oct 2020 14:53:21

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '09:57'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered '22 Oct 2020 09:57'	System	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '65'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'bpm'	System	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '16'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'breaths/min'	System	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '133'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'mmHg'	System	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '71'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'mmHg'	System	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '11:15'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered '22 Oct 2020 11:15'	System	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '37.1' C	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '65'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'bpm'	System	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '16'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'breaths/min'	System	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '129'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'mmHg'	System	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '77'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'mmHg'	System	23 Oct 2020 14:21:43

US3712114

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:53:36

US3712114

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:53:36

US3712114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:54:51

US3712114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:54:51

US3712114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:54:51

US3712114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'MRNA-1273 OR PLACEBO'	System	22 Oct 2020 14:54:51

US3712114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:54:51

US3712114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '10:45'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:54:51

US3712114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered '22 Oct 2020 10:45'	System	22 Oct 2020 14:54:51

US3712114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:54:51

US3712114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'ONCE'	System	22 Oct 2020 14:54:51

US3712114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'INTRAMUSCULAR'	System	22 Oct 2020 14:54:51

US3712114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:53:54

US3712114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:53:54

US3712114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '10:10'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:53:54

US3712114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered '22 Oct 2020 10:10'	System	22 Oct 2020 14:53:54

US3712114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:27:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:54:04

US3712114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:27:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Oct 2020 14:54:04

US3712114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:54:04

US3712114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:27:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '10:12'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:54:04

US3712114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:27:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered '22 Oct 2020 10:12'	System	22 Oct 2020 14:54:04

US3712114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:27:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Oct 2020 14:54:04

US3712114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 21:08:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 21:08:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:54:04

US3712114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:27:55

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:13:08
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 21:08:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 21:08:53
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '10:12'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:54:04

US3712114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:27:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered empty.	System	15 Feb 2021 21:08:53
User entered '22 Oct 2020 10:12'	System	22 Oct 2020 14:54:04

US3712114

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:54:09

US3712114

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'I'	System	22 Oct 2020 14:54:09

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T11:37:12', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '28d560f3-56e7-478c-8979-c12e2655f9c5' User entered 'Yes (Y)'	System	22 Oct 2020 15:37:40
	System	22 Oct 2020 15:37:40

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T11:37:24', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '28d560f3-56e7-478c-8979-c12e2655f9c5' User entered '98.7'	System	22 Oct 2020 15:37:40
	System	22 Oct 2020 15:37:40

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T11:37:29', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '28d560f3-56e7-478c-8979-c12e2655f9c5'	System	22 Oct 2020 15:37:40
User entered 'No (N)'	System	22 Oct 2020 15:37:40

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T11:37:38', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '28d560f3-56e7-478c-8979-c12e2655f9c5' User entered '22 Oct 2020 11:37'	System	22 Oct 2020 15:37:40
	System	22 Oct 2020 15:37:40

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '22 Oct 2020 11:05'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '22 Oct 2020 13:35'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T20:58:17', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '94e1a3a4-24e6-40cc-8db4-bf667cda4208'	System	23 Oct 2020 00:59:01
User entered 'Yes (Y)'	System	23 Oct 2020 00:59:01

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T20:58:27', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '94e1a3a4-24e6-40cc-8db4-bf667cda4208' User entered '97.4'	System	23 Oct 2020 00:59:01
	System	23 Oct 2020 00:59:01

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T20:58:34', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '94e1a3a4-24e6-40cc-8db4-bf667cda4208'	System	23 Oct 2020 00:59:01
User entered 'No (N)'	System	23 Oct 2020 00:59:01

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T20:58:59', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '94e1a3a4-24e6-40cc-8db4-bf667cda4208'	System	23 Oct 2020 00:59:01
User entered '22 Oct 2020 20:58'	System	23 Oct 2020 00:59:01

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '22 Oct 2020 14:30'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 2'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-23T22:38:11', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '693e76c5-3896-40b4-b4b7-a61f1415d51c' User entered 'Yes (Y)'	System	24 Oct 2020 02:38:43
	System	24 Oct 2020 02:38:43

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-23T22:38:20', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '693e76c5-3896-40b4-b4b7-a61f1415d51c' User entered '97.6'	System	24 Oct 2020 02:38:43
	System	24 Oct 2020 02:38:43

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-23T22:38:31', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '693e76c5-3896-40b4-b4b7-a61f1415d51c' User entered 'No (N)'	System	24 Oct 2020 02:38:43
	System	24 Oct 2020 02:38:43

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-23T22:38:41', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '693e76c5-3896-40b4-b4b7-a61f1415d51c' User entered '23 Oct 2020 22:38'	System	24 Oct 2020 02:38:43
	System	24 Oct 2020 02:38:43

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 3'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:27:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T00:09:34', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '8892a26a-e374-4707-bb98-a20f11a48912' User entered 'Yes (Y)'	System	25 Oct 2020 04:10:02
	System	25 Oct 2020 04:10:02

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T00:09:50', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '8892a26a-e374-4707-bb98-a20f11a48912' User entered '97.0'	System	25 Oct 2020 04:10:02
	System	25 Oct 2020 04:10:02

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T00:09:54', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '8892a26a-e374-4707-bb98-a20f11a48912'	System	25 Oct 2020 04:10:02
User entered 'No (N)'	System	25 Oct 2020 04:10:02

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T00:09:57', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '8892a26a-e374-4707-bb98-a20f11a48912' User entered '25 Oct 2020 00:09'	System	25 Oct 2020 04:10:02
	System	25 Oct 2020 04:10:02

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 4'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:27:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T22:09:13', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '69794b2a-41fd-4361-a8a6-fb357014dbdf' User entered 'Yes (Y)'	System	26 Oct 2020 02:09:33
	System	26 Oct 2020 02:09:33

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T22:09:22', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '69794b2a-41fd-4361-a8a6-fb357014dbdf' User entered '97.1'	System	26 Oct 2020 02:09:33
	System	26 Oct 2020 02:09:33

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T22:09:27', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '69794b2a-41fd-4361-a8a6-fb357014dbdf' User entered 'No (N)'	System	26 Oct 2020 02:09:33
	System	26 Oct 2020 02:09:33

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T22:09:31', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '69794b2a-41fd-4361-a8a6-fb357014dbdf' User entered '25 Oct 2020 22:09'	System	26 Oct 2020 02:09:33
	System	26 Oct 2020 02:09:33

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 5'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:27:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-26T23:03:13', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '5933b971-d164-414b-8916-91885f3bc914'	System	27 Oct 2020 03:04:19
User entered 'Yes (Y)'	System	27 Oct 2020 03:04:19

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-26T23:04:05', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '5933b971-d164-414b-8916-91885f3bc914' User entered '97.1'	System	27 Oct 2020 03:04:19
	System	27 Oct 2020 03:04:19

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-26T23:04:09', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '5933b971-d164-414b-8916-91885f3bc914'	System	27 Oct 2020 03:04:19
User entered 'No (N)'	System	27 Oct 2020 03:04:19

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-26T23:04:14', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '5933b971-d164-414b-8916-91885f3bc914' User entered '26 Oct 2020 23:04'	System	27 Oct 2020 03:04:19
	System	27 Oct 2020 03:04:19

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 6'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:27:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-27T22:01:05', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '46d57595-b1d7-4d21-8761-27e8895e0949'	System	28 Oct 2020 02:02:40
User entered 'Yes (Y)'	System	28 Oct 2020 02:02:40

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-27T22:02:26', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '46d57595-b1d7-4d21-8761-27e8895e0949' User entered '97.1'	System	28 Oct 2020 02:02:40
	System	28 Oct 2020 02:02:40

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-27T22:02:31', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '46d57595-b1d7-4d21-8761-27e8895e0949'	System	28 Oct 2020 02:02:40
User entered 'No (N)'	System	28 Oct 2020 02:02:40

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-27T22:02:35', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '46d57595-b1d7-4d21-8761-27e8895e0949'	System	28 Oct 2020 02:02:40
User entered '27 Oct 2020 22:02'	System	28 Oct 2020 02:02:40

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 7'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-28T21:19:56', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '7737b307-7117-4e64-8d3c-344714d4c83a'	System	29 Oct 2020 01:20:14
User entered 'Yes (Y)'	System	29 Oct 2020 01:20:14

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-28T21:20:04', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '7737b307-7117-4e64-8d3c-344714d4c83a' User entered '96.8'	System	29 Oct 2020 01:20:14
	System	29 Oct 2020 01:20:14

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-28T21:20:07', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '7737b307-7117-4e64-8d3c-344714d4c83a'	System	29 Oct 2020 01:20:14
User entered 'No (N)'	System	29 Oct 2020 01:20:14

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-28T21:20:10', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '7737b307-7117-4e64-8d3c-344714d4c83a'	System	29 Oct 2020 01:20:14
User entered '28 Oct 2020 21:20'	System	29 Oct 2020 01:20:14

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T11:33:37', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c39ad313-26c6-4efc-8f12-2d95efbfd057'	System	22 Oct 2020 15:34:10
User entered 'None (1)'	System	22 Oct 2020 15:34:10

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T11:33:51', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c39ad313-26c6-4efc-8f12-2d95efbfd057'	System	22 Oct 2020 15:34:10
User entered 'No (N)'	System	22 Oct 2020 15:34:10

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T11:33:54', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c39ad313-26c6-4efc-8f12-2d95efbfd057'	System	22 Oct 2020 15:34:10
User entered 'No (N)'	System	22 Oct 2020 15:34:10

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T11:33:57', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c39ad313-26c6-4efc-8f12-2d95efbfd057'	System	22 Oct 2020 15:34:10
User entered 'None (1)'	System	22 Oct 2020 15:34:10

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T11:34:04', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c39ad313-26c6-4efc-8f12-2d95efbfd057'	System	22 Oct 2020 15:34:10
User entered '22 Oct 2020 11:34'	System	22 Oct 2020 15:34:10

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '22 Oct 2020 11:05'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '22 Oct 2020 13:35'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T20:59:09', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2155ada1-9c46-4ac4-881f-d90411805e39'	System	23 Oct 2020 00:59:32
User entered 'None (1)'	System	23 Oct 2020 00:59:32

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T20:59:14', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2155ada1-9c46-4ac4-881f-d90411805e39'	System	23 Oct 2020 00:59:32
User entered 'No (N)'	System	23 Oct 2020 00:59:32

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T20:59:19', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2155ada1-9c46-4ac4-881f-d90411805e39' User entered 'No (N)'	System	23 Oct 2020 00:59:32
	System	23 Oct 2020 00:59:32

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T20:59:25', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2155ada1-9c46-4ac4-881f-d90411805e39'	System	23 Oct 2020 00:59:32
User entered 'None (1)'	System	23 Oct 2020 00:59:32

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T20:59:29', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2155ada1-9c46-4ac4-881f-d90411805e39' User entered '22 Oct 2020 20:59'	System	23 Oct 2020 00:59:32
	System	23 Oct 2020 00:59:32

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '22 Oct 2020 14:30'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 2'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-23T22:38:49', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fa9513a5-a433-4a93-af0d-de37a9577c3a' User entered 'None (1)'	System	24 Oct 2020 02:39:41
	System	24 Oct 2020 02:39:41

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-23T22:39:14', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fa9513a5-a433-4a93-af0d-de37a9577c3a' User entered 'No (N)'	System	24 Oct 2020 02:39:41
	System	24 Oct 2020 02:39:41

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-23T22:39:18', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fa9513a5-a433-4a93-af0d-de37a9577c3a' User entered 'No (N)'	System	24 Oct 2020 02:39:41
	System	24 Oct 2020 02:39:41

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-23T22:39:22', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fa9513a5-a433-4a93-af0d-de37a9577c3a' User entered 'None (1)'	System	24 Oct 2020 02:39:41
	System	24 Oct 2020 02:39:41

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-23T22:39:39', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fa9513a5-a433-4a93-af0d-de37a9577c3a' User entered '23 Oct 2020 22:39'	System	24 Oct 2020 02:39:41
	System	24 Oct 2020 02:39:41

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 3'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T00:10:06', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'cdf8cfe7-2e7a-4d7e-ae52-db3a3eac9e42'	System	25 Oct 2020 04:10:25
User entered 'None (1)'	System	25 Oct 2020 04:10:25

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T00:10:10', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'cdf8cfe7-2e7a-4d7e-ae52-db3a3eac9e42'	System	25 Oct 2020 04:10:25
User entered 'No (N)'	System	25 Oct 2020 04:10:25

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T00:10:14', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'cdf8cfe7-2e7a-4d7e-ae52-db3a3eac9e42'	System	25 Oct 2020 04:10:25
User entered 'No (N)'	System	25 Oct 2020 04:10:25

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T00:10:18', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'cdf8cfe7-2e7a-4d7e-ae52-db3a3eac9e42'	System	25 Oct 2020 04:10:25
User entered 'None (1)'	System	25 Oct 2020 04:10:25

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T00:10:21', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'cdf8cfe7-2e7a-4d7e-ae52-db3a3eac9e42'	System	25 Oct 2020 04:10:25
User entered '25 Oct 2020 00:10'	System	25 Oct 2020 04:10:25

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 4'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T22:09:38', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fb365de3-ada6-4c50-824a-f3b07a5af5b4' User entered 'None (1)'	System	26 Oct 2020 02:09:53
	System	26 Oct 2020 02:09:53

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T22:09:41', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fb365de3-ada6-4c50-824a-f3b07a5af5b4' User entered 'No (N)'	System	26 Oct 2020 02:09:53
	System	26 Oct 2020 02:09:53

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T22:09:44', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fb365de3-ada6-4c50-824a-f3b07a5af5b4' User entered 'No (N)'	System	26 Oct 2020 02:09:53
	System	26 Oct 2020 02:09:53

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T22:09:47', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fb365de3-ada6-4c50-824a-f3b07a5af5b4' User entered 'None (1)'	System	26 Oct 2020 02:09:53
	System	26 Oct 2020 02:09:53

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T22:09:51', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fb365de3-ada6-4c50-824a-f3b07a5af5b4' User entered '25 Oct 2020 22:09'	System	26 Oct 2020 02:09:53
	System	26 Oct 2020 02:09:53

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 5'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-26T23:04:20', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '091f7685-91d1-4f71-bd3a-de7aed783da1' User entered 'None (1)'	System	27 Oct 2020 03:05:02
	System	27 Oct 2020 03:05:02

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-26T23:04:32', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '091f7685-91d1-4f71-bd3a-de7aed783da1' User entered 'No (N)'	System	27 Oct 2020 03:05:02
	System	27 Oct 2020 03:05:02

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-26T23:04:35', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '091f7685-91d1-4f71-bd3a-de7aed783da1' User entered 'No (N)'	System	27 Oct 2020 03:05:02
	System	27 Oct 2020 03:05:02

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-26T23:04:45', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '091f7685-91d1-4f71-bd3a-de7aed783da1' User entered 'None (1)'	System	27 Oct 2020 03:05:02
	System	27 Oct 2020 03:05:02

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-26T23:05:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '091f7685-91d1-4f71-bd3a-de7aed783da1' User entered '26 Oct 2020 23:05'	System	27 Oct 2020 03:05:02
	System	27 Oct 2020 03:05:02

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 6'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-27T22:02:42', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '87271c26-2363-440f-95d3-2b17fe6a83cb' User entered 'None (1)'	System	28 Oct 2020 02:03:03
	System	28 Oct 2020 02:03:03

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-27T22:02:45', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '87271c26-2363-440f-95d3-2b17fe6a83cb' User entered 'No (N)'	System	28 Oct 2020 02:03:03
	System	28 Oct 2020 02:03:03

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-27T22:02:49', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '87271c26-2363-440f-95d3-2b17fe6a83cb' User entered 'No (N)'	System	28 Oct 2020 02:03:03
	System	28 Oct 2020 02:03:03

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-27T22:02:53', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '87271c26-2363-440f-95d3-2b17fe6a83cb' User entered 'None (1)'	System	28 Oct 2020 02:03:03
	System	28 Oct 2020 02:03:03

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-27T22:02:57', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '87271c26-2363-440f-95d3-2b17fe6a83cb' User entered '27 Oct 2020 22:02'	System	28 Oct 2020 02:03:03
	System	28 Oct 2020 02:03:03

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 7'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-28T21:20:17', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '6e8173eb-5a45-4772-a22f-63068c06077e'	System	29 Oct 2020 01:20:38
User entered 'None (1)'	System	29 Oct 2020 01:20:38

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-28T21:20:21', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '6e8173eb-5a45-4772-a22f-63068c06077e' User entered 'No (N)'	System	29 Oct 2020 01:20:38
	System	29 Oct 2020 01:20:38

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-28T21:20:23', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '6e8173eb-5a45-4772-a22f-63068c06077e' User entered 'No (N)'	System	29 Oct 2020 01:20:38
	System	29 Oct 2020 01:20:38

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-28T21:20:27', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '6e8173eb-5a45-4772-a22f-63068c06077e' User entered 'None (1)'	System	29 Oct 2020 01:20:38
	System	29 Oct 2020 01:20:38

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-28T21:20:30', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '6e8173eb-5a45-4772-a22f-63068c06077e' User entered '28 Oct 2020 21:20'	System	29 Oct 2020 01:20:38
	System	29 Oct 2020 01:20:38

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T11:34:10', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '308179cf-2f38-49df-b95b-8c0872aef67b' User entered 'None (0)'	System	22 Oct 2020 15:35:20
	System	22 Oct 2020 15:35:20

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T11:34:17', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '308179cf-2f38-49df-b95b-8c0872aef67b' User entered 'None (0)'	System	22 Oct 2020 15:35:20
	System	22 Oct 2020 15:35:20

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T11:34:21', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '308179cf-2f38-49df-b95b-8c0872aef67b' User entered 'None (0)'	System	22 Oct 2020 15:35:20
	System	22 Oct 2020 15:35:20

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T11:34:27', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '308179cf-2f38-49df-b95b-8c0872aef67b' User entered 'None (0)'	System	22 Oct 2020 15:35:20
	System	22 Oct 2020 15:35:20

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T11:34:37', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '308179cf-2f38-49df-b95b-8c0872aef67b' User entered 'None (0)'	System	22 Oct 2020 15:35:20
	System	22 Oct 2020 15:35:20

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T11:34:39', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '308179cf-2f38-49df-b95b-8c0872aef67b' User entered 'None (0)'	System	22 Oct 2020 15:35:20
	System	22 Oct 2020 15:35:20

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T11:35:12', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '308179cf-2f38-49df-b95b-8c0872aef67b'	System	22 Oct 2020 15:35:20
User entered 'No (N)'	System	22 Oct 2020 15:35:20

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T11:35:18', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '308179cf-2f38-49df-b95b-8c0872aef67b' User entered '22 Oct 2020 11:35'	System	22 Oct 2020 15:35:20
	System	22 Oct 2020 15:35:20

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '22 Oct 2020 11:05'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '22 Oct 2020 13:35'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T20:59:36', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '1ea907cd-780e-43ae-bf38-14514203d620' User entered 'None (0)'	System	23 Oct 2020 01:00:19
	System	23 Oct 2020 01:00:19

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T20:59:48', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '1ea907cd-780e-43ae-bf38-14514203d620' User entered 'None (0)'	System	23 Oct 2020 01:00:19
	System	23 Oct 2020 01:00:19

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T20:59:52', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '1ea907cd-780e-43ae-bf38-14514203d620' User entered 'None (0)'	System	23 Oct 2020 01:00:19
	System	23 Oct 2020 01:00:19

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T20:59:55', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '1ea907cd-780e-43ae-bf38-14514203d620' User entered 'None (0)'	System	23 Oct 2020 01:00:19
	System	23 Oct 2020 01:00:19

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T21:00:01', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '1ea907cd-780e-43ae-bf38-14514203d620' User entered 'None (0)'	System	23 Oct 2020 01:00:19
	System	23 Oct 2020 01:00:19

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T21:00:04', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '1ea907cd-780e-43ae-bf38-14514203d620' User entered 'None (0)'	System	23 Oct 2020 01:00:19
	System	23 Oct 2020 01:00:19

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T21:00:10', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '1ea907cd-780e-43ae-bf38-14514203d620' User entered 'No (N)'	System	23 Oct 2020 01:00:19
	System	23 Oct 2020 01:00:19

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-22T21:00:12', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '1ea907cd-780e-43ae-bf38-14514203d620' User entered '22 Oct 2020 21:00'	System	23 Oct 2020 01:00:19
	System	23 Oct 2020 01:00:19

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '22 Oct 2020 14:30'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 2'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-23T22:39:47', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '16da66eb-dcc0-4724-813a-dc059cf9755c' User entered 'None (0)'	System	24 Oct 2020 02:41:13
	System	24 Oct 2020 02:41:13

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-23T22:40:19', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '16da66eb-dcc0-4724-813a-dc059cf9755c' User entered 'None (0)'	System	24 Oct 2020 02:41:13
	System	24 Oct 2020 02:41:13

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-23T22:40:42', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '16da66eb-dcc0-4724-813a-dc059cf9755c' User entered 'None (0)'	System	24 Oct 2020 02:41:13
	System	24 Oct 2020 02:41:13

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-23T22:40:47', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '16da66eb-dcc0-4724-813a-dc059cf9755c' User entered 'None (0)'	System	24 Oct 2020 02:41:13
	System	24 Oct 2020 02:41:13

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-23T22:40:51', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '16da66eb-dcc0-4724-813a-dc059cf9755c' User entered 'None (0)'	System	24 Oct 2020 02:41:13
	System	24 Oct 2020 02:41:13

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-23T22:40:57', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '16da66eb-dcc0-4724-813a-dc059cf9755c' User entered 'None (0)'	System	24 Oct 2020 02:41:13
	System	24 Oct 2020 02:41:13

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-23T22:41:02', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '16da66eb-dcc0-4724-813a-dc059cf9755c' User entered 'No (N)'	System	24 Oct 2020 02:41:13
	System	24 Oct 2020 02:41:13

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-23T22:41:07', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '16da66eb-dcc0-4724-813a-dc059cf9755c' User entered '23 Oct 2020 22:41'	System	24 Oct 2020 02:41:13
	System	24 Oct 2020 02:41:13

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 3'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T00:10:31', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'd863596c-e254-46f3-a0be-39f93efc795d' User entered 'None (0)'	System	25 Oct 2020 04:11:13
	System	25 Oct 2020 04:11:13

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T00:10:37', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'd863596c-e254-46f3-a0be-39f93efc795d' User entered 'None (0)'	System	25 Oct 2020 04:11:13
	System	25 Oct 2020 04:11:13

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T00:10:42', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'd863596c-e254-46f3-a0be-39f93efc795d' User entered 'None (0)'	System	25 Oct 2020 04:11:13
	System	25 Oct 2020 04:11:13

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T00:10:56', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'd863596c-e254-46f3-a0be-39f93efc795d' User entered 'None (0)'	System	25 Oct 2020 04:11:13
	System	25 Oct 2020 04:11:13

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T00:10:59', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'd863596c-e254-46f3-a0be-39f93efc795d' User entered 'None (0)'	System	25 Oct 2020 04:11:13
	System	25 Oct 2020 04:11:13

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T00:11:02', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'd863596c-e254-46f3-a0be-39f93efc795d' User entered 'None (0)'	System	25 Oct 2020 04:11:13
	System	25 Oct 2020 04:11:13

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T00:11:07', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'd863596c-e254-46f3-a0be-39f93efc795d' User entered 'No (N)'	System	25 Oct 2020 04:11:13
	System	25 Oct 2020 04:11:13

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T00:11:10', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'd863596c-e254-46f3-a0be-39f93efc795d' User entered '25 Oct 2020 00:11'	System	25 Oct 2020 04:11:13
	System	25 Oct 2020 04:11:13

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 4'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T22:09:56', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e0fad5ba-42bf-40f4-b06e-ad2f29647c46' User entered 'None (0)'	System	26 Oct 2020 02:10:27
	System	26 Oct 2020 02:10:27

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T22:09:59', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e0fad5ba-42bf-40f4-b06e-ad2f29647c46' User entered 'None (0)'	System	26 Oct 2020 02:10:27
	System	26 Oct 2020 02:10:27

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T22:10:05', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e0fad5ba-42bf-40f4-b06e-ad2f29647c46' User entered 'None (0)'	System	26 Oct 2020 02:10:27
	System	26 Oct 2020 02:10:27

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T22:10:08', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e0fad5ba-42bf-40f4-b06e-ad2f29647c46' User entered 'None (0)'	System	26 Oct 2020 02:10:27
	System	26 Oct 2020 02:10:27

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T22:10:11', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e0fad5ba-42bf-40f4-b06e-ad2f29647c46' User entered 'None (0)'	System	26 Oct 2020 02:10:27
	System	26 Oct 2020 02:10:27

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T22:10:14', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e0fad5ba-42bf-40f4-b06e-ad2f29647c46' User entered 'None (0)'	System	26 Oct 2020 02:10:27
	System	26 Oct 2020 02:10:27

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T22:10:20', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e0fad5ba-42bf-40f4-b06e-ad2f29647c46' User entered 'No (N)'	System	26 Oct 2020 02:10:27
	System	26 Oct 2020 02:10:27

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-25T22:10:24', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e0fad5ba-42bf-40f4-b06e-ad2f29647c46' User entered '25 Oct 2020 22:10'	System	26 Oct 2020 02:10:27
	System	26 Oct 2020 02:10:27

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 5'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-26T23:05:06', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '64a182ca-ce40-4954-a883-6f7bea47ab45' User entered 'None (0)'	System	27 Oct 2020 03:05:32
	System	27 Oct 2020 03:05:32

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-26T23:05:09', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '64a182ca-ce40-4954-a883-6f7bea47ab45' User entered 'None (0)'	System	27 Oct 2020 03:05:32
	System	27 Oct 2020 03:05:32

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-26T23:05:12', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '64a182ca-ce40-4954-a883-6f7bea47ab45' User entered 'None (0)'	System	27 Oct 2020 03:05:32
	System	27 Oct 2020 03:05:32

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-26T23:05:15', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '64a182ca-ce40-4954-a883-6f7bea47ab45' User entered 'None (0)'	System	27 Oct 2020 03:05:32
	System	27 Oct 2020 03:05:32

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-26T23:05:19', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '64a182ca-ce40-4954-a883-6f7bea47ab45' User entered 'None (0)'	System	27 Oct 2020 03:05:32
	System	27 Oct 2020 03:05:32

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-26T23:05:22', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '64a182ca-ce40-4954-a883-6f7bea47ab45' User entered 'None (0)'	System	27 Oct 2020 03:05:32
	System	27 Oct 2020 03:05:32

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-26T23:05:25', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '64a182ca-ce40-4954-a883-6f7bea47ab45' User entered 'No (N)'	System	27 Oct 2020 03:05:32
	System	27 Oct 2020 03:05:32

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-26T23:05:28', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '64a182ca-ce40-4954-a883-6f7bea47ab45' User entered '26 Oct 2020 23:05'	System	27 Oct 2020 03:05:32
	System	27 Oct 2020 03:05:32

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 6'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-27T22:03:07', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c1eef55c-9c09-417d-aecd-8242e691aeb5' User entered 'None (0)'	System	28 Oct 2020 02:03:34
	System	28 Oct 2020 02:03:34

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-27T22:03:10', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c1eef55c-9c09-417d-aecd-8242e691aeb5' User entered 'None (0)'	System	28 Oct 2020 02:03:34
	System	28 Oct 2020 02:03:34

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-27T22:03:12', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c1eef55c-9c09-417d-aecd-8242e691aeb5' User entered 'None (0)'	System	28 Oct 2020 02:03:34
	System	28 Oct 2020 02:03:34

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-27T22:03:15', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c1eef55c-9c09-417d-aecd-8242e691aeb5' User entered 'None (0)'	System	28 Oct 2020 02:03:34
	System	28 Oct 2020 02:03:34

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-27T22:03:18', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c1eef55c-9c09-417d-aecd-8242e691aeb5' User entered 'None (0)'	System	28 Oct 2020 02:03:34
	System	28 Oct 2020 02:03:34

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-27T22:03:23', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c1eef55c-9c09-417d-aecd-8242e691aeb5' User entered 'None (0)'	System	28 Oct 2020 02:03:34
	System	28 Oct 2020 02:03:34

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-27T22:03:26', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c1eef55c-9c09-417d-aecd-8242e691aeb5' User entered 'No (N)'	System	28 Oct 2020 02:03:34
	System	28 Oct 2020 02:03:34

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-27T22:03:30', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c1eef55c-9c09-417d-aecd-8242e691aeb5' User entered '27 Oct 2020 22:03'	System	28 Oct 2020 02:03:34
	System	28 Oct 2020 02:03:34

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
Data entry locked.	System	22 Oct 2020 14:54:51
User entered 'Day 7'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-28T21:20:36', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2e24bd9b-cb2e-44bd-adab-716eb205f470' User entered 'None (0)'	System	29 Oct 2020 01:20:58
	System	29 Oct 2020 01:20:58

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-28T21:20:38', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2e24bd9b-cb2e-44bd-adab-716eb205f470' User entered 'None (0)'	System	29 Oct 2020 01:20:58
	System	29 Oct 2020 01:20:58

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-28T21:20:40', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2e24bd9b-cb2e-44bd-adab-716eb205f470' User entered 'None (0)'	System	29 Oct 2020 01:20:58
	System	29 Oct 2020 01:20:58

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-28T21:20:43', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2e24bd9b-cb2e-44bd-adab-716eb205f470' User entered 'None (0)'	System	29 Oct 2020 01:20:58
	System	29 Oct 2020 01:20:58

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-28T21:20:45', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2e24bd9b-cb2e-44bd-adab-716eb205f470' User entered 'None (0)'	System	29 Oct 2020 01:20:58
	System	29 Oct 2020 01:20:58

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-28T21:20:48', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2e24bd9b-cb2e-44bd-adab-716eb205f470' User entered 'None (0)'	System	29 Oct 2020 01:20:58
	System	29 Oct 2020 01:20:58

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

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 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-28T21:20:52', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2e24bd9b-cb2e-44bd-adab-716eb205f470' User entered 'No (N)'	System	29 Oct 2020 01:20:58
	System	29 Oct 2020 01:20:58

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-10-28T21:20:55', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '2e24bd9b-cb2e-44bd-adab-716eb205f470' User entered '28 Oct 2020 21:20'	System	29 Oct 2020 01:20:58
	System	29 Oct 2020 01:20:58

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 14:54:51

US3712114

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:41:42
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 14:54:51

US3712114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:46

US3712114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:46

US3712114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:46

US3712114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:46

US3712114

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:48

US3712114

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User entered 'I'	System	02 Nov 2020 13:11:48

US3712114

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:56:38

US3712114

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '05 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:56:38

US3712114

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:56:38

US3712114

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:56:38

US3712114

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:56:40

US3712114

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User entered 'I'	System	09 Nov 2020 18:56:40

US3712114

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:44:40

US3712114

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:44:40

US3712114

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:44:40

US3712114

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:44:40

US3712114

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:44:44

US3712114

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User entered 'I'	System	02 Dec 2020 21:44:44

US3712114

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:44:55

US3712114

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '24 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:44:55

US3712114

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:44:55

US3712114

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'VISIT3'	System	02 Dec 2020 21:44:55

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:45:15

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:45:15

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:45:15

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered empty.	System	02 Dec 2020 21:45:15

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:45:15

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:45:15

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:45:15

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:45:15

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered empty.	System	02 Dec 2020 21:45:15

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:45:15

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered empty.	System	02 Dec 2020 21:45:15

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:45:15

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered empty.	System	02 Dec 2020 21:45:15

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:45:15

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered empty.	System	02 Dec 2020 21:45:15

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08

US3712114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08

US3712114

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:45:18

US3712114

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:45:18

US3712114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:45:26

US3712114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '24 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:45:26

US3712114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered '11:22'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:45:26

US3712114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered '24 Nov 2020 11:22'	System	02 Dec 2020 21:45:26

US3712114

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User signature succeeded.	William Smith (b) (4)	13 Feb 2021 00:28:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 21:45:28

US3712114

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:37:08
User entered 'I'	System	02 Dec 2020 21:45:28

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-11-21T17:02:17', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '441c3364-78a5-491f-bd02-22f2ddee5e34'	System	21 Nov 2020 22:03:55
User entered 'Yes (Y)'	System	21 Nov 2020 22:03:55

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-11-21T17:02:24', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '441c3364-78a5-491f-bd02-22f2ddee5e34'	System	21 Nov 2020 22:03:55
User entered 'No (N)'	System	21 Nov 2020 22:03:55

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-11-21T17:02:28', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '441c3364-78a5-491f-bd02-22f2ddee5e34'	System	21 Nov 2020 22:03:55
User entered 'No (N)'	System	21 Nov 2020 22:03:55

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-11-21T17:03:07', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '441c3364-78a5-491f-bd02-22f2ddee5e34'	System	21 Nov 2020 22:03:55
User entered 'Yes (Y)'	System	21 Nov 2020 22:03:55

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Please 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-11-21T17:03:18', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '441c3364-78a5-491f-bd02-22f2ddee5e34'	System	21 Nov 2020 22:03:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Nov 2020 22:03:55

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-11-21T17:03:45', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '441c3364-78a5-491f-bd02-22f2ddee5e34' User entered '21 Nov 2020 17:03:45'	System	21 Nov 2020 22:03:55
	System	21 Nov 2020 22:03:55

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-11-30T04:42:46', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e3e424a0-3452-458a-aa0f-65bca141a2f6'	System	30 Nov 2020 09:43:02
User entered 'No (N)'	System	30 Nov 2020 09:43:02

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-11-30T04:42:53', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e3e424a0-3452-458a-aa0f-65bca141a2f6'	System	30 Nov 2020 09:43:02
User entered 'No (N)'	System	30 Nov 2020 09:43:02

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-11-30T04:42:58', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e3e424a0-3452-458a-aa0f-65bca141a2f6' User entered '30 Nov 2020 04:42:58'	System	30 Nov 2020 09:43:02

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-12-05T00:07:45', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '67f3cfdc-5e20-48a8-a8cf-f6ed2973681c' User entered 'No (N)'	System	06 Dec 2020 20:01:55
	System	06 Dec 2020 20:01:55

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-12-05T00:07:52', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '67f3cfdc-5e20-48a8-a8cf-f6ed2973681c' User entered 'No (N)'	System	06 Dec 2020 20:01:55

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-12-05T00:07:56', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '67f3cfdc-5e20-48a8-a8cf-f6ed2973681c' User entered '05 Dec 2020 00:07:56'	System	06 Dec 2020 20:01:55

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-12-13T14:57:16', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c13c8ce6-2b19-48ee-a3c4-6676f01e4e3b'	System	13 Dec 2020 19:57:44
User entered 'No (N)'	System	13 Dec 2020 19:57:44

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-12-13T14:57:31', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c13c8ce6-2b19-48ee-a3c4-6676f01e4e3b'	System	13 Dec 2020 19:57:44
User entered 'No (N)'	System	13 Dec 2020 19:57:44

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-12-13T14:57:36', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c13c8ce6-2b19-48ee-a3c4-6676f01e4e3b' User entered '13 Dec 2020 14:57:36'	System	13 Dec 2020 19:57:44
	System	13 Dec 2020 19:57:44

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-12-19T00:01:58', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '89e95b25-bb11-4034-a5ee-daea2f04885d' User entered 'No (N)'	System	19 Dec 2020 05:03:01
	System	19 Dec 2020 05:03:01

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-12-19T00:02:17', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '89e95b25-bb11-4034-a5ee-daea2f04885d' User entered 'No (N)'	System	19 Dec 2020 05:03:01
	System	19 Dec 2020 05:03:01

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-12-19T00:02:21', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '89e95b25-bb11-4034-a5ee-daea2f04885d' User entered '19 Dec 2020 00:02:21'	System	19 Dec 2020 05:03:01
	System	19 Dec 2020 05:03:01

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-12-26T13:21:17', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fc0755bc-dcba-4383-9796-c4ded3b57e82'	System	26 Dec 2020 18:21:47
User entered 'No (N)'	System	26 Dec 2020 18:21:47

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-12-26T13:21:41', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fc0755bc-dcba-4383-9796-c4ded3b57e82'	System	26 Dec 2020 18:21:47
User entered 'No (N)'	System	26 Dec 2020 18:21:47

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2020-12-26T13:21:44', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fc0755bc-dcba-4383-9796-c4ded3b57e82' User entered '26 Dec 2020 13:21:44'	System	26 Dec 2020 18:21:47
	System	26 Dec 2020 18:21:47

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-01-03T15:55:01', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'afdf169a-2451-4c95-b8fd-74c18aa0b7fb' User entered 'No (N)'	System	03 Jan 2021 20:55:16
	System	03 Jan 2021 20:55:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-01-03T15:55:06', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'afdf169a-2451-4c95-b8fd-74c18aa0b7fb' User entered 'No (N)'	System	03 Jan 2021 20:55:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-01-03T15:55:12', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'afdf169a-2451-4c95-b8fd-74c18aa0b7fb' User entered '03 Jan 2021 15:55:12'	System	03 Jan 2021 20:55:16
	System	03 Jan 2021 20:55:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-01-09T00:08:36', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e3260bc6-a670-4b18-b892-a9c64f25624b' User entered 'No (N)'	System	09 Jan 2021 05:08:53
	System	09 Jan 2021 05:08:53

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-01-09T00:08:46', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e3260bc6-a670-4b18-b892-a9c64f25624b' User entered 'No (N)'	System	09 Jan 2021 05:08:53

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-01-09T00:08:50', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'e3260bc6-a670-4b18-b892-a9c64f25624b' User entered '09 Jan 2021 00:08:50'	System	09 Jan 2021 05:08:53
	System	09 Jan 2021 05:08:53

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-01-19T14:30:10', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '697f3cde-7712-4f65-8ffb-617fcdeb1c1c'	System	19 Jan 2021 19:30:24
User entered 'No (N)'	System	19 Jan 2021 19:30:24

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-01-19T14:30:14', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '697f3cde-7712-4f65-8ffb-617fcdeb1c1c' User entered 'No (N)'	System	19 Jan 2021 19:30:24
	System	19 Jan 2021 19:30:24

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-01-19T14:30:21', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '697f3cde-7712-4f65-8ffb-617fcdeb1c1c' User entered '19 Jan 2021 14:30:21'	System	19 Jan 2021 19:30:24
	System	19 Jan 2021 19:30:24

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-01-24T11:32:49', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '00e69fba-86fb-444e-a4eb-c383912e2e15'	System	24 Jan 2021 16:33:04
User entered 'No (N)'	System	24 Jan 2021 16:33:04

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-01-24T11:32:57', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '00e69fba-86fb-444e-a4eb-c383912e2e15'	System	24 Jan 2021 16:33:04
User entered 'No (N)'	System	24 Jan 2021 16:33:04

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-01-24T11:33:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '00e69fba-86fb-444e-a4eb-c383912e2e15' User entered '24 Jan 2021 11:33:00'	System	24 Jan 2021 16:33:04
	System	24 Jan 2021 16:33:04

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-01-30T00:02:26', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fd6ab33e-c796-4a02-82e1-433c772fe2e1'	System	30 Jan 2021 05:03:53
User entered 'No (N)'	System	30 Jan 2021 05:03:53

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-01-30T00:02:29', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fd6ab33e-c796-4a02-82e1-433c772fe2e1'	System	30 Jan 2021 05:03:53
User entered 'No (N)'	System	30 Jan 2021 05:03:53

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-01-30T00:02:33', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'fd6ab33e-c796-4a02-82e1-433c772fe2e1' User entered '30 Jan 2021 00:02:33'	System	30 Jan 2021 05:03:53
	System	30 Jan 2021 05:03:53

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-02-08T12:00:50', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '62c7a561-11e0-46c4-ac34-80a7134561ef' User entered 'No (N)'	System	08 Feb 2021 17:03:55
	System	08 Feb 2021 17:03:55

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-02-08T12:00:57', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '62c7a561-11e0-46c4-ac34-80a7134561ef' User entered 'No (N)'	System	08 Feb 2021 17:03:55

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-02-08T12:01:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '62c7a561-11e0-46c4-ac34-80a7134561ef' User entered '08 Feb 2021 12:01:00'	System	08 Feb 2021 17:03:55
	System	08 Feb 2021 17:03:55

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-02-13T12:55:47', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'dcc5252e-a617-4d07-8c14-79417e3cd64c' User entered 'No (N)'	System	13 Feb 2021 17:55:54
	System	13 Feb 2021 17:55:54

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-02-13T12:55:50', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'dcc5252e-a617-4d07-8c14-79417e3cd64c' User entered 'No (N)'	System	13 Feb 2021 17:55:54
	System	13 Feb 2021 17:55:54

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-02-13T12:55:52', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'dcc5252e-a617-4d07-8c14-79417e3cd64c' User entered '13 Feb 2021 12:55:52'	System	13 Feb 2021 17:55:54
	System	13 Feb 2021 17:55:54

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-02-22T16:37:52', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '02f28cb2-d8d0-49fa-b93f-50b16f7d9c49'	System	22 Feb 2021 21:38:10
User entered 'No (N)'	System	22 Feb 2021 21:38:10

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-02-22T16:37:55', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '02f28cb2-d8d0-49fa-b93f-50b16f7d9c49'	System	22 Feb 2021 21:38:10
User entered 'No (N)'	System	22 Feb 2021 21:38:10

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-02-22T16:38:07', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '02f28cb2-d8d0-49fa-b93f-50b16f7d9c49'	System	22 Feb 2021 21:38:10
User entered '22 Feb 2021 16:38:07'	System	22 Feb 2021 21:38:10

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-02-27T07:49:03-05:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'ad4f8f38-e2e4-4725-88e6-1f735e89c1a7'	System	27 Feb 2021 12:49:13
User entered 'No (N)'	System	27 Feb 2021 12:49:13

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-02-27T07:49:05-05:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'ad4f8f38-e2e4-4725-88e6-1f735e89c1a7'	System	27 Feb 2021 12:49:13
User entered 'No (N)'	System	27 Feb 2021 12:49:13

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-02-27T07:49:09-05:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'ad4f8f38-e2e4-4725-88e6-1f735e89c1a7'	System	27 Feb 2021 12:49:13
User entered '27 Feb 2021 12:49:09'	System	27 Feb 2021 12:49:13

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-03-09T11:49:29-05:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '3d0f58a6-dc69-4c8e-9402-b437bc681317'	System	09 Mar 2021 16:49:38
User entered 'No (N)'	System	09 Mar 2021 16:49:38

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-03-09T11:49:31-05:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '3d0f58a6-dc69-4c8e-9402-b437bc681317'	System	09 Mar 2021 16:49:38
User entered 'No (N)'	System	09 Mar 2021 16:49:38

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-03-09T11:49:34-05:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '3d0f58a6-dc69-4c8e-9402-b437bc681317' User entered '09 Mar 2021 11:49:34'	System	09 Mar 2021 16:49:38
	System	09 Mar 2021 16:49:38

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-03-13T19:02:18-05:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '7d0d94cc-3e82-408b-bcef-5544838cb51f'	System	14 Mar 2021 00:06:46
User entered 'No (N)'	System	14 Mar 2021 00:06:46

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-03-13T19:04:03-05:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '7d0d94cc-3e82-408b-bcef-5544838cb51f'	System	14 Mar 2021 00:06:46
User entered 'No (N)'	System	14 Mar 2021 00:06:46

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-03-13T19:04:37-05:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '7d0d94cc-3e82-408b-bcef-5544838cb51f' User entered '13 Mar 2021 19:04:37'	System	14 Mar 2021 00:06:46
	System	14 Mar 2021 00:06:46

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-03-22T11:08:55-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '27c1eabd-5da0-4839-887f-886212ff5e22'	System	22 Mar 2021 15:09:22
User entered 'No (N)'	System	22 Mar 2021 15:09:22

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-03-22T11:08:59-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '27c1eabd-5da0-4839-887f-886212ff5e22'	System	22 Mar 2021 15:09:22
User entered 'No (N)'	System	22 Mar 2021 15:09:22

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-03-22T11:09:19-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '27c1eabd-5da0-4839-887f-886212ff5e22'	System	22 Mar 2021 15:09:22
User entered '22 Mar 2021 11:09:19'	System	22 Mar 2021 15:09:22

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-03-27T00:02:33-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'f1c63071-535a-428a-a972-fafcdc227f45'	System	27 Mar 2021 04:07:54
User entered 'No (N)'	System	27 Mar 2021 04:07:54

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-03-27T00:02:39-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'f1c63071-535a-428a-a972-fafcdc227f45'	System	27 Mar 2021 04:07:54
User entered 'No (N)'	System	27 Mar 2021 04:07:54

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-03-27T00:02:41-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'f1c63071-535a-428a-a972-fafcdc227f45' User entered '27 Mar 2021 00:02:41'	System	27 Mar 2021 04:07:54
	System	27 Mar 2021 04:07:54

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-04-03T00:02:26-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'bcb1e45c-3ccc-435d-a296-f739aabfa441'	System	03 Apr 2021 04:03:48
User entered 'No (N)'	System	03 Apr 2021 04:03:48

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-04-03T00:02:31-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'bcb1e45c-3ccc-435d-a296-f739aabfa441'	System	03 Apr 2021 04:03:48
User entered 'No (N)'	System	03 Apr 2021 04:03:48

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-04-03T00:02:34-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'bcb1e45c-3ccc-435d-a296-f739aabfa441' User entered '03 Apr 2021 00:02:34'	System	03 Apr 2021 04:03:48
	System	03 Apr 2021 04:03:48

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-04-11T15:17:44-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '586a696a-1881-4c50-822d-de110c8d2f41'	System	11 Apr 2021 19:17:53
User entered 'No (N)'	System	11 Apr 2021 19:17:53

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-04-11T15:17:46-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '586a696a-1881-4c50-822d-de110c8d2f41'	System	11 Apr 2021 19:17:53
User entered 'No (N)'	System	11 Apr 2021 19:17:53

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-04-11T15:17:49-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: '586a696a-1881-4c50-822d-de110c8d2f41'	System	11 Apr 2021 19:17:53
User entered '11 Apr 2021 15:17:49'	System	11 Apr 2021 19:17:53

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-04-17T00:34:59-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'cd1be823-6dd7-4e52-b452-dbb63dea8964'	System	17 Apr 2021 04:35:10
User entered 'No (N)'	System	17 Apr 2021 04:35:10

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-04-17T00:35:03-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'cd1be823-6dd7-4e52-b452-dbb63dea8964'	System	17 Apr 2021 04:35:10
User entered 'No (N)'	System	17 Apr 2021 04:35:10

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-04-17T00:35:06-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'cd1be823-6dd7-4e52-b452-dbb63dea8964'	System	17 Apr 2021 04:35:10
User entered '17 Apr 2021 00:35:06'	System	17 Apr 2021 04:35:10

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-04-26T12:00:32-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c7baf10c-f034-46e0-bb40-cba07feeb2d9'	System	26 Apr 2021 16:02:12
User entered 'No (N)'	System	26 Apr 2021 16:02:12

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-04-26T12:00:37-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c7baf10c-f034-46e0-bb40-cba07feeb2d9'	System	26 Apr 2021 16:02:12
User entered 'No (N)'	System	26 Apr 2021 16:02:12

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-04-26T12:00:40-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'c7baf10c-f034-46e0-bb40-cba07feeb2d9' User entered '26 Apr 2021 12:00:40'	System	26 Apr 2021 16:02:12
	System	26 Apr 2021 16:02:12

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-05-01T10:48:40-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'd2812398-2b15-4b33-b792-abb5809e0c20'	System	01 May 2021 14:48:49
User entered 'No (N)'	System	01 May 2021 14:48:49

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Have you been exposed to someone with 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 (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-05-01T10:48:44-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'd2812398-2b15-4b33-b792-abb5809e0c20'	System	01 May 2021 14:48:49
User entered 'No (N)'	System	01 May 2021 14:48:49

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-05-01T10:48:47-04:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'd2812398-2b15-4b33-b792-abb5809e0c20'	System	01 May 2021 14:48:49
User entered '01 May 2021 10:48:47'	System	01 May 2021 14:48:49

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 08:52:16

US3712114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:52:16
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 08:52:16

US3712114

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:27:55

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 22:46:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-02-27T07:49:31-05:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'ccf51109-bbe7-4cdb-ab8e-a6f8950524ea'	System	27 Feb 2021 12:50:10
User entered 'No (N)'	System	27 Feb 2021 12:50:10

US3712114

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:27:55

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:46:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6AE8A0E-050C-4FC4-BF56-DACC51C0D3CE)', Time: '2021-02-27T07:49:49-05:00', User OID: 'PatientReportedOutcome (US3712114)', ODM File OID: 'ccf51109-bbe7-4cdb-ab8e-a6f8950524ea' User entered '27 Feb 2021 12:49:49'	System	27 Feb 2021 12:50:10
	System	27 Feb 2021 12:50:10

US3712114

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:32:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:21:24

US3712114

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:32:20
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:21:24

US3712114

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:32:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:21:24

US3712114

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:32:20
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:21:24

US3712114

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:32:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:21:27

US3712114

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:36:49
User entered 'I'	System	19 Jan 2021 20:21:27

US3712114

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 15:55:16

US3712114

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
User entered '18 Jan 2021'	(b) (4), (b) (6)	01 Feb 2021 15:55:16

US3712114

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Feb 2021 15:55:16

US3712114

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 15:55:16

US3712114

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 15:55:18

US3712114

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User entered 'I'	System	01 Feb 2021 15:55:18

US3712114

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 20:45:07

US3712114

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
User entered '20 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 20:45:07

US3712114

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Feb 2021 20:45:07

US3712114

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 20:45:07

US3712114

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 20:45:09

US3712114

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User entered 'I'	System	22 Feb 2021 20:45:09

US3712114

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Mar 2021 13:34:12

US3712114

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
User entered '22 Mar 2021'	(b) (4), (b) (6)	23 Mar 2021 13:34:12

US3712114

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Mar 2021 13:34:12

US3712114

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 13:34:12

US3712114

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Mar 2021 13:34:14

US3712114

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:44:27
User entered 'I'	System	23 Mar 2021 13:34:14

US3712114

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

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:46:34

US3712114

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

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:46:34

US3712114

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

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:46:34

US3712114

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

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'UNBLND_DECIDE'	System	05 Feb 2021 21:46:34

US3712114

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

Form: Unblinding

Generated On: 10 Jun 2021 09:27:55

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:03:41
User entered '06 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 21:47:34

US3712114

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

Form: Unblinding

Generated On: 10 Jun 2021 09:27:55

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:09:08

US3712114

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

Form: Unblinding

Generated On: 10 Jun 2021 09:27:55

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:47:34

US3712114

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

Form: Unblinding

Generated On: 10 Jun 2021 09:27:55

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:09:08

US3712114

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

Form: Unblinding

Generated On: 10 Jun 2021 09:27:55

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:47:34

US3712114

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

Form: Unblinding

Generated On: 10 Jun 2021 09:27:55

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:47:34

US3712114

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

Form: Unblinding

Generated On: 10 Jun 2021 09:27:55

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:47:34

US3712114

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

Form: Unblinding

Generated On: 10 Jun 2021 09:27:55

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:47:34

US3712114

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

Form: Unblinding

Generated On: 10 Jun 2021 09:27:55

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:47:34

US3712114

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

Form: Unblinding

Generated On: 10 Jun 2021 09:27:55

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered '1'	System	05 Feb 2021 21:47:34

US3712114

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

Form: Unblinding

Generated On: 10 Jun 2021 09:27:55

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'I'	System	05 Feb 2021 21:47:34

US3712114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered empty.	System	05 Feb 2021 21:48:13
DataPoint set to visible.	System	05 Feb 2021 21:47:34

US3712114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered empty.	System	05 Feb 2021 21:48:13
DataPoint set to visible.	System	05 Feb 2021 21:47:34

US3712114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '09:05'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered '01 Feb 2021 09:05'	System	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '71'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'bpm'	System	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'breaths/min'	System	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '126'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'mmHg'	System	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '70'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'mmHg'	System	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered empty.	System	05 Feb 2021 21:48:13
DataPoint set to visible.	System	05 Feb 2021 21:47:34

US3712114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '10:24'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered '01 Feb 2021 10:24'	System	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '64'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'bpm'	System	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'breaths/min'	System	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '139'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'mmHg'	System	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '79'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:13

US3712114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'mmHg'	System	05 Feb 2021 21:48:13

US3712114

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:19

US3712114

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:19

US3712114

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

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:42

US3712114

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

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:42

US3712114

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

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:42

US3712114

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

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'mRNA-1273'	System	05 Feb 2021 21:48:42
DataPoint set to visible.	System	05 Feb 2021 21:47:34

US3712114

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

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:42

US3712114

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

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '09:54'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:42

US3712114

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

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered '01 Feb 2021 09:54'	System	05 Feb 2021 21:48:42

US3712114

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

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:48:42

US3712114

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

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'ONCE'	System	05 Feb 2021 21:48:42

US3712114

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

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'INTRAMUSCULAR'	System	05 Feb 2021 21:48:42

US3712114

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:47:09

US3712114

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:47:09

US3712114

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '08:56'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:47:09

US3712114

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered '01 Feb 2021 08:56'	System	05 Feb 2021 21:47:09

US3712114

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:47:17

US3712114

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:47:17

US3712114

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:27:55

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '08:59'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:47:17

US3712114

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:27:55

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered '01 Feb 2021 08:59'	System	05 Feb 2021 21:47:17

US3712114

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

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:04:13

US3712114

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

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'I'	System	22 Feb 2021 15:04:13

US3712114

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:04:36

US3712114

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:04:36

US3712114

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:04:36

US3712114

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:04:36

US3712114

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:04:38

US3712114

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'I'	System	22 Feb 2021 15:04:38

US3712114

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered '1'	System	22 Feb 2021 15:04:38
DataPoint set to visible.	System	22 Feb 2021 15:04:38

US3712114

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:33:13

US3712114

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:33:13

US3712114

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:33:13

US3712114

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'OLD29'	System	05 Mar 2021 19:33:13

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '08:08'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered '02 Mar 2021 08:08'	System	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '74'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'bpm'	System	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '14'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'breaths/min'	System	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '135'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'mmHg'	System	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '72'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'mmHg'	System	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '09:21'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered '02 Mar 2021 09:21'	System	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '65'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'bpm'	System	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'breaths/min'	System	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '133'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'mmHg'	System	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '75'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'mmHg'	System	05 Mar 2021 19:34:07

US3712114

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:11

US3712114

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:11

US3712114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:27

US3712114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:27

US3712114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:27

US3712114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'mRNA-1273'	System	05 Mar 2021 19:34:27
DataPoint set to visible.	System	22 Feb 2021 15:04:38

US3712114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:27

US3712114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered '08:51'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:27

US3712114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered '02 Mar 2021 08:51'	System	05 Mar 2021 19:34:27

US3712114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:27

US3712114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'ONCE'	System	05 Mar 2021 19:34:27

US3712114

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:55

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'INTRAMUSCULAR'	System	05 Mar 2021 19:34:27

US3712114

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:34:34

US3712114

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'I'	System	05 Mar 2021 19:34:34

US3712114

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 13:35:36

US3712114

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 13:35:36

US3712114

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 13:35:36

US3712114

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 13:35:36

US3712114

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 13:35:38

US3712114

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:12:17
User entered 'I'	System	23 Mar 2021 13:35:38

US3712114

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:27:55

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:15
User signature succeeded.	William Smith (b) (4)	12 Mar 2021 22:22:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:04:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 18:26:10

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	26 Feb 2021 19:04:38
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:56:57
User entered	System	17 Feb 2021 13:56:11
'USA-US068-2021-mRNA-1273-P301000012'		
User entered 'New'	(b) (4), (b) (6)	17 Feb 2021 13:56:11

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
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: Progression of prostate cancer - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 07:07:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 07:07:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:03:23
Data point term sent to Coder	System	21 Apr 2021 14:45:39
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 14:44:53
Coding entries removed.	(b) (4), (b) (6)	21 Apr 2021 14:44:53
User entered 'progression PROSTATE CANCER' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 14:44:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:04:38
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)	26 Oct 2020 19:29:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:29:43
Data point term sent to Coder	System	26 Oct 2020 18:29:46
User entered 'prostate cancer'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:42:13
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User closed query 'PV Query: Per the reported onset date the event occurred prior to subject enrollment in the study. Please consider deleting the event and adding to medical history, else reconcile the start date. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:17:02
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:03:21
Query 'PV Query: Per the reported onset date the event occurred prior to subject enrollment in the study. Please consider deleting the event and adding to medical history, else reconcile the start date. ' answered with 'date has been updated' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:45:23
User closed query 'Adverse Event Start Date is before System treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).		21 Apr 2021 14:39:33
User closed query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).		21 Apr 2021 14:39:33
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 14:39:33
User opened query 'PV Query: Per the reported onset date the event occurred prior to subject enrollment in the study. Please consider deleting the event and adding to medical history, else reconcile the start date. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 20:53:23
User closed query 'PV Query: Please confirm event start date. Paper SAE form indicates the biopsy was performed on 14 Jul 2020 and revealed stage one and two prostate cancer; however, the event start date is not until 01 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 19:27:33

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm event start date. Paper SAE form indicates the biopsy was performed on 14 Jul 2020 and revealed stage one and two prostate cancer; however, the event start date is not until 01 Oct 2020.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:23:11
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	13 Apr 2021 17:22:55
User opened query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).		13 Apr 2021 17:22:55
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:22:55
User entered '14 Jul 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 17:22:55
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User opened query 'PV Query: Please confirm event start date. Paper SAE form indicates the biopsy was performed on 14 Jul 2020 and revealed stage one and two prostate cancer; however, the event start date is not until 01 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 19:58:36
User entered '01 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 21:28:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 21:28:55
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	26 Feb 2021 19:04:38
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 15:03:27
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 19:12:38
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	05 Mar 2021 19:12:38
reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Feb 2021 15:04:07
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Feb 2021 15:00:30
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 15:00:30
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 15:03:36
User closed query 'Per paper report, this is considered "life threatening"' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 13:45:12
Query 'Per paper report, this is considered "life threatening"' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 19:08:46
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 19:07:53
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User opened query 'Per paper report, this is considered "life threatening"' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 18:54:23
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	21 Apr 2021 15:03:36
	(b) (4), (b) (6)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	12 Apr 2021 13:45:39
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	12 Apr 2021 13:45:39
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:45:39
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	05 Mar 2021 19:19:38
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:19:38
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	05 Mar 2021 19:08:35
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	05 Mar 2021 19:08:35
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:08:35
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	05 Mar 2021 19:07:53
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 19:07:53
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:04:38

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	18 Feb 2021 17:06:23
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		18 Feb 2021 17:06:23
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	18 Feb 2021 17:05:02
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 17:05:02
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 17:05:02
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 15:03:36
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If so, please reassess the reported seriousness criterion of hospitalization, as it was answered "no".' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:57:08
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If so, please reassess the reported seriousness criterion of hospitalization, as it was answered "no".' answered with 'seriousness has been changed to yes ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:46:39
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If so, please reassess the reported seriousness criterion of hospitalization, as it was answered "no".' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 17:02:46
User closed query 'PV Query: Please confirm hospital discharge date discrepancy. EDC reports 14 Dec 2020; paper SAE form reports 14 Nov 2020. Please update EDC if paper SAE form is correct.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 16:37:25
Query 'PV Query: Please confirm hospital discharge date discrepancy. EDC reports 14 Dec 2020; paper SAE form reports 14 Nov 2020. Please update EDC if paper SAE form is correct.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 19:08:53
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 19:07:53
User entered '14 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:04:38
Query 'Please review this discharge month as it seems to have been Nov. If confirmed, please update canceled (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 19:02:37
User opened query 'Please review this discharge month as it seems to have been Nov. If confirmed, please update' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 19:02:28

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm hospital discharge date discrepancy. EDC reports 14 Dec 2020; paper SAE form reports 14 Nov 2020. Please update EDC if paper SAE form is correct.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 19:57:53
User entered '14 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 17:05:02
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 17:06:23
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 15:04:07
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 15:03:36
User closed query 'PV Query: As the last dose of Placebo was given on 22 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:57:17
Query 'PV Query: As the last dose of Placebo was given on 22 Oct 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:47:09
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 13:45:39
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:45:39
User opened query 'PV Query: As the last dose of Placebo was given on 22 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 17:03:19
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered 'None (NONE)'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

Concomitant Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 04:07:17
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:03:36
User closed query 'Please confirm, con meds were given for this event. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:28:58
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'ccmeds have been added ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 16:32:38
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 02:04:45
Query 'Please confirm, con meds were given for this event. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 19:08:59
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 19:07:53
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User opened query 'Please confirm, con meds were given for this event. ' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 19:03:41
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

PRODUCTION RELEASE (v12.003
EAB) (1725)

1993 of 2565

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:04:38
User closed query 'Per CDM: Concomitant Procedure is checked however corresponding Concomitant Procedure page is blank. Please review and update accordingly.	(b) (4), (b) (6)	01 Feb 2021 17:10:51
' (Site from DM). Query 'Per CDM: Concomitant Procedure is checked however corresponding Concomitant Procedure page is blank. Please review and update accordingly.	(b) (4), (b) (6)	29 Jan 2021 19:12:03
' answered with 'updated' (Site from DM). User opened query 'Per CDM: Concomitant Procedure is checked however corresponding Concomitant Procedure page is blank. Please review and update accordingly.	(b) (4), (b) (6)	11 Dec 2020 17:30:34
' (Site from DM). User entered 'I'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	02 Dec 2020 21:28:55
Data Entry Error		
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
DataPoint Verified.	(b) (4)	21 Apr 2021 15:03:36
	(b) (4), (b) (6)	
User closed query 'PV Query: Please confirm date of prostate biopsy.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 19:27:43
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 19:27:41
Query 'PV Query: Please confirm date of prostate biopsy.' answered with 'date added ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:23:59
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'No covid testing was done ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:22:55
User entered 'HAD LABS DONE THAT RESULTED IN ABNORMAL PSA. PCP SENT THEM TO HAVE PROSTATE BIOPSY on 14 July 2020 THAT SHOWED STAGE 1 AND 2 PROSTATE CANCER. SUBJECT STATES THEY HAVE NOT HAD ANY MEDICATION AND DEFERRED RADIATION, BUT IS HAVING A PROSTATECTOMY ON 13 NOVEMBER 2020.'	(b) (4), (b) (6)	13 Apr 2021 17:22:55
reason for change: Data Entry Error		
User closed query 'PV Query: Please confirm serious criteria discrepancy. EDC reports hospitalization and other medically important event; paper SAE form reports hospitalization and life-threatening. Please update EDC if paper SAE form is correct.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 16:37:32
User closed query 'PV Query: Please confirm event severity discrepancy. EDC reports Grade 2/Moderate; paper SAE form reports Grade 3/Severe. Please update EDC if paper SAE form is correct.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 16:37:29

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm serious criteria discrepancy. EDC reports hospitalization and other medically important event; paper SAE form reports hospitalization and life-threatening. Please update EDC if paper SAE form is correct.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 19:19:50
Query 'PV Query: Please confirm event severity discrepancy. EDC reports Grade 2/Moderate; paper SAE form reports Grade 3/Severe. Please update EDC if paper SAE form is correct.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 19:17:42
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:04:38
User opened query 'PV Query: Please confirm date of prostate biopsy.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 19:58:14
User opened query 'PV Query: Please confirm serious criteria discrepancy. EDC reports hospitalization and other medically important event; paper SAE form reports hospitalization and life-threatening. Please update EDC if paper SAE form is correct.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 19:57:25
User opened query 'PV Query: Please confirm event severity discrepancy. EDC reports Grade 2/Moderate; paper SAE form reports Grade 3/Severe. Please update EDC if paper SAE form is correct.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 19:57:02
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 19:56:42
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Feb 2021 15:03:43
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	16 Feb 2021 15:03:43

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Had labs done that resulted in abnormal PSA. PCP sent them to have prostate biopsy that showed stage 1 and 2 prostate cancer. Subject states they have not had any medication and deferred radiation, but is having a prostatectomy on 13 November 2020.' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 15:03:43
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Feb 2021 15:00:30
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 15:00:30
User entered '0'	System	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 18:42:13
User entered '0'	System	26 Oct 2020 18:29:03

US3712114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
User entered '0'	System	18 Feb 2021 17:06:23

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:27:55

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:06:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:32:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 18:34:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 18:34:39
Data point term sent to Coder	System	28 Sep 2020 18:33:31
User entered 'lisinopril'	(b) (4), (b) (6)	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'hypertension'	(b) (4), (b) (6)	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '30'	(b) (4), (b) (6)	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	26 Feb 2021 19:12:41
	(b) (4), (b) (6)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'un UNK 1989'	(b) (4), (b) (6)	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 18:33:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: EMPAGLIFLOZIN;LINAGLIPTIN, PRODUCTSYNONYM: GLYXAMBI - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:35:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:35:43
Data point term sent to Coder	System	28 Sep 2020 18:34:33
User entered 'glyxambi'	(b) (4), (b) (6)	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'type 2 diabetes'	(b) (4), (b) (6)	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '25-5'	(b) (4), (b) (6)	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'un UNK 1989'	(b) (4), (b) (6)	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 18:34:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	26 Feb 2021 19:12:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: MUCINEX DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 14:59:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 14:59:33
Data point term sent to Coder Coding entries removed.	System	11 Nov 2020 14:58:08
	(b) (4), (b) (6)	11 Nov 2020 14:57:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: MUCINEX DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:37:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:37:50
Data point term sent to Coder	System	28 Sep 2020 18:36:41
User entered 'mucinex dm'	(b) (4), (b) (6)	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:41
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:28:50
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 14:57:50
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'added' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:39:52
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 12:38:15
User entered 'congestion'	(b) (4), (b) (6)	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '1200/60'	(b) (4), (b) (6)	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'as needed (PRN)'	(b) (4), (b) (6)	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'un UNK 2019'	(b) (4), (b) (6)	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:36:35

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:38:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:38:38
Data point term sent to Coder	System	28 Sep 2020 18:37:45
User entered 'loratadine'	(b) (4), (b) (6)	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:41
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:28:54
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'added' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:57:43
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 12:36:47
User entered 'seasonal allergies'	(b) (4), (b) (6)	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '10'	(b) (4), (b) (6)	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	26 Feb 2021 19:12:41
	(b) (4), (b) (6)	
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	26 Feb 2021 19:12:41
User entered '01 Jan 2020'	(b) (4), (b) (6)	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 18:37:13

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:41:17
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	28 Sep 2020 18:41:17
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	28 Sep 2020 18:39:47
User entered 'atorvastatin'	(b) (4), (b) (6)	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'hyperlipidemia'	(b) (4), (b) (6)	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '40'	(b) (4), (b) (6)	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'un UNK 1989'	(b) (4), (b) (6)	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 18:39:02

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:41:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:41:48
Data point term sent to Coder	System	28 Sep 2020 18:40:51
User entered 'metformin'	(b) (4), (b) (6)	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'type 2 diabetes'	(b) (4), (b) (6)	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '500'	(b) (4), (b) (6)	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'twice daily (BID)'	(b) (4), (b) (6)	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'un UNK 1989'	(b) (4), (b) (6)	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 18:40:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:42:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	28 Sep 2020 18:42:38
Data point term sent to Coder	System	28 Sep 2020 18:41:53
User entered 'esomeprazole magnesium'	(b) (4), (b) (6)	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6)	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '20'	(b) (4), (b) (6)	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:41
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:29:02
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:00:42
User entered 'UN UNK 2000' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:00:28
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 12:33:06
User entered 'un UNK 1985'	(b) (4), (b) (6)	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 18:41:30

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DEGLUDEC, PRODUCTSYNONYM: TRESIBA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 02:40:29
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 02:40:29
	(b) (4)	
Data point term sent to Coder	System	28 Sep 2020 18:44:56
User entered 'tresiba insulin pen'	(b) (4), (b) (6)	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'type 2 diabetes'	(b) (4), (b) (6)	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '16'	(b) (4), (b) (6)	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 12:04:44
User entered 'Other (OTHER)'	(b) (4), (b) (6)	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	26 Feb 2021 19:12:41
	(b) (4), (b) (6)	
User closed query 'Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 19:06:03
Query 'Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify' answered with 'Corrected' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:04:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 12:04:44
User opened query 'Per CDM: Dose Unit is recorded as 'Other - UNITS', however, please confirm if Unit can be selected from already available option 'IU'. If so, please update as appropriate, else clarify' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:56:54
User entered 'units '	(b) (4), (b) (6)	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'un UNK 2019'	(b) (4), (b) (6)	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 18:44:27

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:46:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:46:49
Data point term sent to Coder	System	28 Sep 2020 18:45:58
User entered 'multivitamin'	(b) (4), (b) (6)	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:41
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)	12 Nov 2020 19:29:11
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 'updated' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:01:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:00:55
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 12:38:42
User closed query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:13:42
Query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'medication noted as supplement, not a preventative measure' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:48:13
User opened query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:03:39
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'supplement'	(b) (4), (b) (6)	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '2'	(b) (4), (b) (6)	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Other (OTHER)'	(b) (4), (b) (6)	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'gummies'	(b) (4), (b) (6)	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'un UNK 2015'	(b) (4), (b) (6)	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 18:45:01

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:48:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:48:43
Data point term sent to Coder	System	28 Sep 2020 18:48:03
User entered 'gabapentin'	(b) (4), (b) (6)	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'diabetic neuropathy'	(b) (4), (b) (6)	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '400'	(b) (4), (b) (6)	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	26 Feb 2021 19:12:41
	(b) (4), (b) (6)	
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	26 Feb 2021 19:12:41
	(b) (4), (b) (6)	
User closed query 'per CDM: if frequency is as needed, please use drop down menu to select "AS NEEDED", otherwise please clarify' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:35:06
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	06 Oct 2020 15:51:18
Query 'per CDM: if frequency is as needed, please use drop down menu to select "AS NEEDED", otherwise please clarify' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:51:02
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	06 Oct 2020 15:50:53
User entered 'as needed (PRN)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 15:50:53
User opened query 'per CDM: if frequency is as needed, please use drop down menu to select "AS NEEDED", otherwise please clarify' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 14:50:16
User entered 'other (OTHER)'	(b) (4), (b) (6)	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 15:51:18
User entered '1-2 at bedtime as needed'	(b) (4), (b) (6)	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'un UNK 2015'	(b) (4), (b) (6)	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:47:40

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:41
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)	28 Sep 2020 18:49:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 18:49:46
Data point term sent to Coder	System	28 Sep 2020 18:49:07
User entered 'vitamin d3'	(b) (4), (b) (6)	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:41
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)	10 Nov 2020 19:24:23
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 12:53:07
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' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 12:53:03
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 12:39:45
User closed query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:13:47
Query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'medication noted as supplement, not a preventative measure' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:48:33
User opened query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:03:55
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'supplement'	(b) (4), (b) (6)	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '125'	(b) (4), (b) (6)	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'ug (ug)'	(b) (4), (b) (6)	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	26 Feb 2021 19:12:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'un UNK 2015'	(b) (4), (b) (6)	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 18:48:16

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS, PRODUCT: KRILL OIL, PRODUCTSYNONYM: OMEGA 3 KRILL OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 05:32:55
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 05:32:55
	(b) (4)	
Data point term sent to Coder	System	28 Sep 2020 18:49:07
User entered 'omega 3 krill oil'	(b) (4), (b) (6)	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:41
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)	10 Nov 2020 19:24:32
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 12:53:18
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' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 12:53:14
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 12:39:20
User closed query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:18:07
Query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'medication noted as supplement, not a preventative measure' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:48:43
User opened query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:03:59
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'supplement'	(b) (4), (b) (6)	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '500'	(b) (4), (b) (6)	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '01 Jan 2020'	(b) (4), (b) (6)	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 18:49:04

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:50:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	28 Sep 2020 18:50:50
Data point term sent to Coder	System	28 Sep 2020 18:50:09
User entered 'iron'	(b) (4), (b) (6)	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:12:41
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)	10 Nov 2020 19:24:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 12:53:30
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' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 12:53:26
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 12:35:02
User closed query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:18:10
Query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'medication noted as supplement, not a preventative measure' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:48:57
User opened query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:04:05
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'supplement'	(b) (4), (b) (6)	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '65'	(b) (4), (b) (6)	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'un UNK 2018'	(b) (4), (b) (6)	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:12:41
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 18:49:31

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 16:39:44
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 16:39:44
Data point term sent to Coder	System	20 Apr 2021 16:24:11
Data point term sent to Coder	System	20 Apr 2021 16:21:07
User entered 'oxycodone'	(b) (4), (b) (6)	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'PREVENTION OF PAIN after SURGERY WHILE HOSPITALIZED' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:23:43
User entered 'prevention of pain from surgery while hospitalized'	(b) (4), (b) (6)	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '10'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User entered empty.	System	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User entered empty.	System	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:48
User entered empty.	System	20 Apr 2021 16:20:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 19:09:41
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 19:09:41
Data point term sent to Coder	System	20 Apr 2021 16:24:10
Data point term sent to Coder	System	20 Apr 2021 16:22:08
User entered 'ciprofloxacin'	(b) (4), (b) (6)	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'PREVENTION OF INFECTION after SURGERY WHILE HOSPITALIZED' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:23:36
User entered 'prevention of infection from surgery while hospitalized'	(b) (4), (b) (6)	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '400'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User entered empty.	System	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User entered empty.	System	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:52
User entered empty.	System	20 Apr 2021 16:21:50

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
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)	20 Apr 2021 16:24:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 16:24:38
Data point term sent to Coder	System	20 Apr 2021 16:24:10
User entered 'acetaminophen'	(b) (4), (b) (6)	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'prevention of pain after surgery while hospitalized'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '1000'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User entered empty.	System	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User entered empty.	System	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:00
User entered empty.	System	20 Apr 2021 16:23:25

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
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)	21 Apr 2021 07:15:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	21 Apr 2021 07:15:04
Data point term sent to Coder	System	20 Apr 2021 16:25:12
User entered 'zofran'	(b) (4), (b) (6)	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'prevention of nausea while hospitalized'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '4'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User entered empty.	System	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User entered empty.	System	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:04
User entered empty.	System	20 Apr 2021 16:24:24

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
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)	20 Apr 2021 18:38:32
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 18:38:32
Data point term sent to Coder	System	20 Apr 2021 16:26:13
User entered 'acetaminophen '	(b) (4), (b) (6)	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'prevention of pain after surgery while hospitalized '	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '975'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User entered empty.	System	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User entered empty.	System	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:12
User entered empty.	System	20 Apr 2021 16:25:20

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 20:12:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 20:12:46
Data point term sent to Coder	System	20 Apr 2021 16:27:14
User entered 'heparin'	(b) (4), (b) (6)	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'prevention of Deep vein thrombosis while hospitalized'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '5000'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'every 8 hours'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User entered empty.	System	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User entered empty.	System	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:18
User entered empty.	System	20 Apr 2021 16:26:41

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN - version WHODrug-Global-B3\\202003.	(b) (4)	20 Apr 2021 16:40:33
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 16:40:33
Data point term sent to Coder	System	20 Apr 2021 16:28:16
User entered 'oxybutynin'	(b) (4), (b) (6)	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'prevention of bladder spasms after surgery while hospitalized'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '5'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User entered empty.	System	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User entered empty.	System	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:26
User entered empty.	System	20 Apr 2021 16:27:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
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: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Apr 2021 08:32:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:32:23
Data point term sent to Coder	System	20 Apr 2021 16:29:16
User entered 'sodium chloride 0.9%'	(b) (4), (b) (6)	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'prevention of dehydration while hospitalized'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '880.4'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User entered empty.	System	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User entered empty.	System	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:31
User entered empty.	System	20 Apr 2021 16:28:46

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 16:30:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:30:31
Data point term sent to Coder	System	20 Apr 2021 16:30:17
User entered 'lispro insulin'	(b) (4), (b) (6)	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'type 2 diabetes'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '4'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'U'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User entered empty.	System	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User entered empty.	System	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:41
User entered empty.	System	20 Apr 2021 16:29:42

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 12:10:34
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 12:10:34
Data point term sent to Coder	System	21 Apr 2021 11:37:13
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	21 Apr 2021 11:37:12
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	21 Apr 2021 11:37:12
User entered 'PROTONIX (PANTOPRAZOLE SODIUM,CALCIUM STEARATE, CROSPVIDONE,HYPROMELLOSE,IRON OXIDE,MANNITOL, METHACRYLIC ACID COPOLYMER,POLYSORBATE 80,POVIDONE,PROPYLENE GLYCOL,SODIUM CARBONATE,TRIETHYL CITRATE)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 11:36:54
User entered 'PROTONIX(pantoprazole sodium,calcium stearate, crospovidone,hypromellose,iron oxide,mannitol, methacrylic acid copolymer,polysorbate 80,povidone,propylene glycol,sodium carbonate,triethyl citrate' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 11:36:33

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4)	21 Apr 2021 09:34:53
Data point term sent to Coder	System	20 Apr 2021 16:31:18
User entered 'protonix'	(b) (4), (b) (6)	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'prevention of Gastroesophageal reflux disease while hospitalized'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '40'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User entered empty.	System	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User entered empty.	System	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:45
User entered empty.	System	20 Apr 2021 16:30:48

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: OTHER UROLOGICALS, PRODUCT: PHENAZOPYRIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 16:45:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:45:42
Data point term sent to Coder	System	20 Apr 2021 16:32:19
User entered 'phenazopyridine'	(b) (4), (b) (6)	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'prevention of painful urination after surgery while hospitalized'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '200'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User entered empty.	System	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User entered empty.	System	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:27:53
User entered empty.	System	20 Apr 2021 16:31:36

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
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.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 16:32:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:32:33
Data point term sent to Coder	System	20 Apr 2021 16:32:19
User entered 'cholecalciferol'	(b) (4), (b) (6)	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'supplement'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '5000'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User entered empty.	System	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User entered empty.	System	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:28:00
User entered empty.	System	20 Apr 2021 16:32:12

US3712114

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:27:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 18:29:11

US3712114

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:27:55

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:28:42
User entered '13 Nov 2020'	(b) (4), (b) (6)	29 Jan 2021 19:11:44

US3712114

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:27:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
User closed query 'Please consider the term "Robotic assisted laparoscopic radial prostatectomy with bilateral pelvic lymph node dissection" ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:27
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:22
Query 'Please consider the term "Robotic assisted laparoscopic radial prostatectomy with bilateral pelvic lymph node dissection" ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 19:24:56
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 19:24:50
User entered 'Robotic assisted laparoscopic radial prostatectomy with bilateral pelvic lymph node dissection' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:24:50
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:28:42
User opened query 'Please consider the term "Robotic assisted laparoscopic radial prostatectomy with bilateral pelvic lymph node dissection" ' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 18:28:37
User entered 'prostate cancer removal'	(b) (4), (b) (6)	29 Jan 2021 19:11:44

US3712114

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:28:42
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	29 Jan 2021 19:11:44

US3712114

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:27:55

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:28:42
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 19:11:44

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered	System	17 Feb 2021 13:56:11
'USA-US068-2021-MRNA-1273-P301000012'		

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Yes (Y)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:34
User closed query 'please confirm, SAE was marked as life threatening as well as the others.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:53:32
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:37:57
Query 'please confirm, SAE was marked as life threatening as well as the others.' answered with 'just life threatening ' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 19:23:04
Un-reviewed for Safety.	System	05 Mar 2021 19:07:53
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered 'Yes (Y)'	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User opened query 'please confirm, SAE was marked as life threatening as well as the others.' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 19:05:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:37
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:29:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:28:22
Un-reviewed for Safety.	System	12 Apr 2021 13:45:39
Signature has been broken.	System	12 Apr 2021 13:45:39
User entered 'Yes (Y)'	System	12 Apr 2021 13:45:39
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'No (N)'	System	05 Mar 2021 19:19:38
User entered 'Yes (Y)'	System	05 Mar 2021 19:08:35
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered 'No (N)'	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Un-reviewed for Safety.	System	18 Feb 2021 17:05:02
User entered 'Yes (Y)'	System	18 Feb 2021 17:05:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Yes (Y)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'William'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Smith'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:44
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered '801 north weisgarber' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'Knoxville' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'TN' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered (b) (4)	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:44
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered (b) (4) '	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:46:43
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:46:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered (b) (4)	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:37:57
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'US'	System	17 Feb 2021 13:58:53

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Apr 2021 18:17:21
User entered '4'	System	13 Apr 2021 19:28:35
User entered '3'	System	08 Mar 2021 16:38:12
User entered '2'	System	18 Feb 2021 20:12:29
User entered '1'	System	17 Feb 2021 13:58:53

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
DataPoint Verified.	(b) (4)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'USA-US068-2021-MRNA-1273-P301000012'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Yes (Y)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:34
User closed query 'please confirm, SAE was marked as life threatening as well as the others.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:53:32
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:37:57
Query 'please confirm, SAE was marked as life threatening as well as the others.' answered with 'just life threatening ' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 19:23:04
Un-reviewed for Safety.	System	05 Mar 2021 19:07:53
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered 'Yes (Y)'	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User opened query 'please confirm, SAE was marked as life threatening as well as the others.' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 19:05:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:37
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:29:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:28:22
Un-reviewed for Safety.	System	12 Apr 2021 13:45:39
Signature has been broken.	System	12 Apr 2021 13:45:39
User entered 'Yes (Y)'	System	12 Apr 2021 13:45:39
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'No (N)'	System	05 Mar 2021 19:19:38
User entered 'Yes (Y)'	System	05 Mar 2021 19:08:35
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered 'No (N)'	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Un-reviewed for Safety.	System	18 Feb 2021 17:05:02
User entered 'Yes (Y)'	System	18 Feb 2021 17:05:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Yes (Y)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'William'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Smith'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:44
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered '801 north weisgarber' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'Knoxville' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'TN' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered (b) (4)	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:44
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered (b) (4) '	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:46:43
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:46:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered (b) (4) '	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:37:57
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'US'	System	17 Feb 2021 13:58:53

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Apr 2021 18:17:21
User entered '4'	System	13 Apr 2021 19:28:35
User entered '3'	System	08 Mar 2021 16:38:12
User entered '2'	System	18 Feb 2021 20:12:29
User entered '1'	System	17 Feb 2021 13:58:53

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:27:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered '17/Feb/2021 07:58'	System	17 Feb 2021 13:58:53

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:27:55

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 00:07:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:37:57
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'I'	(b) (4), (b) (6)	17 Feb 2021 13:58:53

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered	System	17 Feb 2021 13:56:11
'USA-US068-2021-MRNA-1273-P301000012'		

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Yes (Y)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:34
User closed query 'please confirm, SAE was marked as life threatening as well as the others.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:53:32
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:37:57
Query 'please confirm, SAE was marked as life threatening as well as the others.' answered with 'just life threatening ' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 19:23:04
Un-reviewed for Safety.	System	05 Mar 2021 19:07:53
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered 'Yes (Y)'	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User opened query 'please confirm, SAE was marked as life threatening as well as the others.' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 19:05:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:37
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:29:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:28:22
Un-reviewed for Safety.	System	12 Apr 2021 13:45:39
Signature has been broken.	System	12 Apr 2021 13:45:39
User entered 'Yes (Y)'	System	12 Apr 2021 13:45:39
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'No (N)'	System	05 Mar 2021 19:19:38
User entered 'Yes (Y)'	System	05 Mar 2021 19:08:35
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered 'No (N)'	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Un-reviewed for Safety.	System	18 Feb 2021 17:05:02
User entered 'Yes (Y)'	System	18 Feb 2021 17:05:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Yes (Y)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'William'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Smith'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:44
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered '801 north weisgarber' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'Knoxville' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'TN' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered (b) (4)	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:44
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered (b) (4)	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:46:43
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:46:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered (b) (4) '	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:37:57
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'US'	System	17 Feb 2021 13:58:53

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Apr 2021 18:17:21
User entered '4'	System	13 Apr 2021 19:28:35
User entered '3'	System	08 Mar 2021 16:38:12
User entered '2'	System	18 Feb 2021 20:12:29
User entered '1'	System	17 Feb 2021 13:58:53

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:27:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered '18/Feb/2021 15:12'	System	18 Feb 2021 20:12:29

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:27:55

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 00:07:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:37:57
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 20:12:29

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered	System	17 Feb 2021 13:56:11
'USA-US068-2021-MRNA-1273-P301000012'		

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Yes (Y)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:34
User closed query 'please confirm, SAE was marked as life threatening as well as the others.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:53:32
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:37:57
Query 'please confirm, SAE was marked as life threatening as well as the others.' answered with 'just life threatening ' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 19:23:04
Un-reviewed for Safety.	System	05 Mar 2021 19:07:53
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered 'Yes (Y)'	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User opened query 'please confirm, SAE was marked as life threatening as well as the others.' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 19:05:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:37
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:29:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:28:22
Un-reviewed for Safety.	System	12 Apr 2021 13:45:39
Signature has been broken.	System	12 Apr 2021 13:45:39
User entered 'Yes (Y)'	System	12 Apr 2021 13:45:39
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'No (N)'	System	05 Mar 2021 19:19:38
User entered 'Yes (Y)'	System	05 Mar 2021 19:08:35
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered 'No (N)'	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Un-reviewed for Safety.	System	18 Feb 2021 17:05:02
User entered 'Yes (Y)'	System	18 Feb 2021 17:05:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Yes (Y)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'William'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Smith'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:44
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered '801 north weisgarber' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'Knoxville' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'TN' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered (b) (4)	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:44
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered (b) (4) '	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:46:43
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:46:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered (b) (4)	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:37:57
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'US'	System	17 Feb 2021 13:58:53

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Apr 2021 18:17:21
User entered '4'	System	13 Apr 2021 19:28:35
User entered '3'	System	08 Mar 2021 16:38:12
User entered '2'	System	18 Feb 2021 20:12:29
User entered '1'	System	17 Feb 2021 13:58:53

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:27:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered '08/Mar/2021 10:38'	(b) (4) System	08 Mar 2021 16:38:12

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:27:55

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)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:38:12

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered	System	17 Feb 2021 13:56:11
'USA-US068-2021-MRNA-1273-P301000012'		

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Yes (Y)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:34
User closed query 'please confirm, SAE was marked as life threatening as well as the others.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:53:32
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:37:57
Query 'please confirm, SAE was marked as life threatening as well as the others.' answered with 'just life threatening ' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 19:23:04
Un-reviewed for Safety.	System	05 Mar 2021 19:07:53
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered 'Yes (Y)'	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User opened query 'please confirm, SAE was marked as life threatening as well as the others.' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 19:05:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:37
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:29:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:28:22
Un-reviewed for Safety.	System	12 Apr 2021 13:45:39
Signature has been broken.	System	12 Apr 2021 13:45:39
User entered 'Yes (Y)'	System	12 Apr 2021 13:45:39
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'No (N)'	System	05 Mar 2021 19:19:38
User entered 'Yes (Y)'	System	05 Mar 2021 19:08:35
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered 'No (N)'	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Un-reviewed for Safety.	System	18 Feb 2021 17:05:02
User entered 'Yes (Y)'	System	18 Feb 2021 17:05:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Yes (Y)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'William'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Smith'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:44
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered '801 north weisgarber' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'Knoxville' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'TN' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered (b) (4)	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:44
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered (b) (4) '	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:46:43
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:46:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered (b) (4) '	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'US'	System	17 Feb 2021 13:58:53

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Apr 2021 18:17:21
User entered '4'	System	13 Apr 2021 19:28:35
User entered '3'	System	08 Mar 2021 16:38:12
User entered '2'	System	18 Feb 2021 20:12:29
User entered '1'	System	17 Feb 2021 13:58:53

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:27:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:29:29
User entered '13/Apr/2021 15:28'	(b) (4) System	13 Apr 2021 19:28:35

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:27:55

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)	21 Apr 2021 14:53:46
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:29:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:28:35

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered	System	17 Feb 2021 13:56:11
'USA-US068-2021-MRNA-1273-P301000012'		

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Yes (Y)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:34
User closed query 'please confirm, SAE was marked as life threatening as well as the others.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:53:32
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:37:57
Query 'please confirm, SAE was marked as life threatening as well as the others.' answered with 'just life threatening ' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 19:23:04
Un-reviewed for Safety.	System	05 Mar 2021 19:07:53
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered 'Yes (Y)'	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User opened query 'please confirm, SAE was marked as life threatening as well as the others.' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 19:05:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:37
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:29:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:28:22
Un-reviewed for Safety.	System	12 Apr 2021 13:45:39
Signature has been broken.	System	12 Apr 2021 13:45:39
User entered 'Yes (Y)'	System	12 Apr 2021 13:45:39
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'No (N)'	System	05 Mar 2021 19:19:38
User entered 'Yes (Y)'	System	05 Mar 2021 19:08:35
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered 'No (N)'	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Un-reviewed for Safety.	System	18 Feb 2021 17:05:02
User entered 'Yes (Y)'	System	18 Feb 2021 17:05:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'No (N)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Yes (Y)'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'William'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered 'Smith'	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:44
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered '801 north weisgarber' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'Knoxville' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered 'TN' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:36
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered empty.	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:46:43

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 19:28:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Un-reviewed for Safety.	(b) (4)	
User entered (b) (4)	System	08 Mar 2021 16:38:12
Reviewed for Safety.	System	08 Mar 2021 16:38:12
	(b) (4), (b) (6)	08 Mar 2021 16:37:57
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:23:44
DataPoint Un-verified.	System	05 Mar 2021 19:07:53
User entered (b) (4) '	System	05 Mar 2021 19:07:53
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:46:43
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:46:43
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 13:57:30
User entered (b) (4) '	System	17 Feb 2021 13:56:11

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:07:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:37:57
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:06:40
User entered 'US'	System	17 Feb 2021 13:58:53

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Apr 2021 18:17:21
User entered '4'	System	13 Apr 2021 19:28:35
User entered '3'	System	08 Mar 2021 16:38:12
User entered '2'	System	18 Feb 2021 20:12:29
User entered '1'	System	17 Feb 2021 13:58:53

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:27:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:40:31
User entered '22/Apr/2021 14:17'	(b) (4) System	22 Apr 2021 18:17:21

US3712114

Folder: SAE USA-US068-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:27:55

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)	23 Apr 2021 21:40:31
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:17:21