

US3712032 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:21:45

All time stamps listed in this document are displayed in GMT

US3712032

Form: Participant Creation

Data signed: (b) (4) 04 Apr 2021 23:54:36

Generated On: 10 Jun 2021 09:21:45

[Participant ID](#)

US3712032

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

US3712032

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:54:52

Generated On: 10 Jun 2021 09:21:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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

US3712032

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

Date of Birth (MMM yyyy)	(b) (6) 1956
Age	64
Age Units	YEARS
Age (Derived)	64
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3712032

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

Date of Informed Consent (<i>dd MMM yyyy</i>)	02 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

US3712032

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3712032

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

Were any significant conditions reported?

Yes ☒

No ☐

US3712032

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

Condition	ALLERGY TO PENICILLIN
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

US3712032

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

Condition	MYOPIA
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3712032

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

Condition	ECZEMA
Start date (dd MMM yyyy)	UN MAR 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)	MAR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3712032

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

Condition	HYPERTENSION
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)	_____

US3712032

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

Condition	HYPERLIPIDEMIA
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)	_____

US3712032

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

Condition	CHOLECYSTITIS
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

US3712032

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

US3712032

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 1978
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 1978
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1978
Start Year (derived)	1978
Stop Month and Year (derived)	JAN 1978
Stop Year (derived)	1978

US3712032

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

Condition	PARTIAL LEFT HIP REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

US3712032

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

Condition	LEFT HIP, BALL AND SOCKET WAS BONE ON BONE
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

US3712032

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

Condition	INGUINAL HERNIA
Start date (dd MMM yyyy)	UN SEP 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 SEP 2018
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2018
Start Year (derived)	2018
Stop Month and Year (derived)	SEP 2018
Stop Year (derived)	2018

US3712032

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

Condition	INGUINAL HERNIA REPAIR
Start date (dd MMM yyyy)	UN SEP 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 SEP 2018
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2018
Start Year (derived)	2018
Stop Month and Year (derived)	SEP 2018
Stop Year (derived)	2018

US3712032

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

Condition	UTERINE ABLATION
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

US3712032

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

Condition	DYSMENORRHEA
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

US3712032

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:54:52

Generated On: 10 Jun 2021 09:21:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	02 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:36 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 13:36
Height (<i>xxx.x</i>)	157.1 cm
Weight (<i>xxx.x</i>)	93.7 lb
BMI (<i>xxx.x</i>)	17.25697 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3712032

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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

US3712032

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

Date of assessment (dd MMM yyyy) 02 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1978

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

US3712032

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

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

DEMAND PLANNER,
RESTAURANTS

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

US3712032

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

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	

US3712032

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:56:15

Generated On: 10 Jun 2021 09:21:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3712032

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 21:54:52

Generated On: 10 Jun 2021 09:21:45

What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 112993

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 ☒

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 21:56:15

Generated On: 10 Jun 2021 09:21:45

Height	157.1 cm
Weight	93.6 kg

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:56:15

Generated On: 10 Jun 2021 09:21:45

Height	157.1 cm
Weight	93.6 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)	10 SEP 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 11:00
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:56:15

Generated On: 10 Jun 2021 09:21:45

Height	157.1 cm
Weight	93.6 kg
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	13:18 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 13:18
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3712032

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:54:52

Generated On: 10 Jun 2021 09:21:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3712032

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:54:52

Generated On: 10 Jun 2021 09:21:45

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 12:48 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 12:48

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

US3712032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:54:52

Generated On: 10 Jun 2021 09:21:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 SEP 2020
Collection time (00:00-23:59)	11:15 (24 HR)
Collection date and time (derived)	10 SEP 2020 11:15

US3712032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 17:09:04

Generated On: 10 Jun 2021 09:21:45

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:17	10 SEP 2020 11:17
Nasopharyngeal Swab 2	No		

US3712032

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:54:52

Generated On: 10 Jun 2021 09:21:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

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

98.1 °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

10 SEP 2020 13:14

PC Open Date & Time

10 SEP 2020 13:08

PC Close Date & Time

10 SEP 2020 15:38

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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

97.7 °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	10 SEP 2020 18:29
PC Open Date & Time	10 SEP 2020 16:33
PC Close Date & Time	11 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

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

97.7 °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

11 SEP 2020 16:38

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 18:43

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:45

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

97.7 °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

13 SEP 2020 20:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 19:24

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:45

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 17:07

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 7

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.7 °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

16 SEP 2020 17:49

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

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

10 SEP 2020 13:14

PC Open Date & Time

10 SEP 2020 13:08

PC Close Date & Time

10 SEP 2020 15:38

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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

10 SEP 2020 18:29

PC Open Date & Time

10 SEP 2020 16:33

PC Close Date & Time

11 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

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

11 SEP 2020 16:38

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

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

12 SEP 2020 18:43

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

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

13 SEP 2020 20:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

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

14 SEP 2020 19:24

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

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

15 SEP 2020 17:07

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

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

16 SEP 2020 17:49

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 13:15
PC Open Date & Time	10 SEP 2020 13:08
PC Close Date & Time	10 SEP 2020 15:38

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 18:30
PC Open Date & Time	10 SEP 2020 16:33
PC Close Date & Time	11 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

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 ☒

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 16:39
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

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)

66 of 2501

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 18:44
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

68 of 2501

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 20:31
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

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

70 of 2501

EAB) (1725)

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 19:25
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

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

72 of 2501

EAB) (1725)

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 17:08
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

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)

74 of 2501

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 17:49
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3712032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712032

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712032

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:56:15

Generated On: 10 Jun 2021 09:21:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 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

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:56:15

Generated On: 10 Jun 2021 09:21:45

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)	07 OCT 2020
Time of assessment (00:00-23:59)	09:45 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 09:45
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:56:15

Generated On: 10 Jun 2021 09:21:45

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	07 OCT 2020
Time of assessment (00:00-23:59)	11:23 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 11:23
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	63 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)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3712032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:56:15

Generated On: 10 Jun 2021 09:21:45

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.

US3712032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:56:15

Generated On: 10 Jun 2021 09:21:45

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) 07 OCT 2020

What was the treatment time? (00:00-23:59) 10:48 (24 HR)

Treatment Date and Time (derived) 07 OCT 2020 10:48

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

US3712032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:56:15

Generated On: 10 Jun 2021 09:21:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 OCT 2020
Collection time (00:00-23:59)	09:49 (24 HR)
Collection date and time (derived)	07 OCT 2020 09:49

US3712032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 17:09:04

Generated On: 10 Jun 2021 09:21:45

Collection date (dd MMM yyyy)			07 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:53	07 OCT 2020 09:53
Nasopharyngeal Swab 2	No		

US3712032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:56:15

Generated On: 10 Jun 2021 09:21:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

07 OCT 2020 11:23

PC Open Date & Time

07 OCT 2020 11:08

PC Close Date & Time

07 OCT 2020 13:38

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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 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	07 OCT 2020 18:04
PC Open Date & Time	07 OCT 2020 14:33
PC Close Date & Time	08 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	08 OCT 2020 17:50
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

09 OCT 2020 19:08

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

10 OCT 2020 20:33

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:45

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

11 OCT 2020 18:05

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 18:49

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:45

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 05:23

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

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

07 OCT 2020 11:24

PC Open Date & Time

07 OCT 2020 11:08

PC Close Date & Time

07 OCT 2020 13:38

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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

07 OCT 2020 18:04

PC Open Date & Time

07 OCT 2020 14:33

PC Close Date & Time

08 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

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

08 OCT 2020 17:50

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

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

09 OCT 2020 19:09

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

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

10 OCT 2020 20:33

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

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

11 OCT 2020 18:05

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

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

12 OCT 2020 18:49

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

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

14 OCT 2020 05:23

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 11:25
PC Open Date & Time	07 OCT 2020 11:08
PC Close Date & Time	07 OCT 2020 13:38

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 18:05
PC Open Date & Time	07 OCT 2020 14:33
PC Close Date & Time	08 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

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)

110 of 2501

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 17:51
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

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

112 of 2501

EAB) (1725)

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 19:10
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

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 ☒

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 20:34
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

116 of 2501

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 18:06
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

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
EAB) (1725)

118 of 2501

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 18:50
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

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)

120 of 2501

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 05:24
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3712032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3712032

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712032

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3712032

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:54:51

Generated On: 10 Jun 2021 09:21:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:56:15

Generated On: 10 Jun 2021 09:21:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:56:15

Generated On: 10 Jun 2021 09:21:45

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) _____

US3712032

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:56:15

Generated On: 10 Jun 2021 09:21:45

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.

US3712032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:56:15

Generated On: 10 Jun 2021 09:21:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 NOV 2020
Collection time (00:00-23:59)	07:46 (24 HR)
Collection date and time (derived)	04 NOV 2020 07:46

US3712032

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:56:15

Generated On: 10 Jun 2021 09:21:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 11:59:40

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3712032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 13:48:50

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 12:01:04
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 12:01:01

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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	12 DEC 2020 12:32:00
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

19 DEC 2020 12:16:51

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 DEC 2020 13:36:24
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 JAN 2021 06:49:19
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	09 JAN 2021 19:45:38
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	18 JAN 2021 13:41:58
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 <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	24 JAN 2021 07:04:51
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 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	01 FEB 2021 12:18:32
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	08 FEB 2021 12:01:03
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	13 FEB 2021 19:55:50
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	22 FEB 2021 12:01:09
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 <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	03 MAR 2021 10:00:39
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

06 MAR 2021 13:03:49

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

13 MAR 2021 06:18:15

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

22 MAR 2021 12:04:40

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

27 MAR 2021 07:59:35

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

03 APR 2021 17:55:25

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

12 APR 2021 12:40:05

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

17 APR 2021 07:52:24

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 07:17:07

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐ Yes ☐

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 <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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	18 AUG 2021 23:59
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US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 376

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	06 OCT 2021 23:59
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US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	27 OCT 2021 23:59
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US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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="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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 439

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 <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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 <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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUL 2022 00:01
Patient Cloud Close Date & Time	27 JUL 2022 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 <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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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="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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:21:45

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		03 MAR 2021 10:00:28

US3712032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 02:28:10

Generated On: 10 Jun 2021 09:21:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712032

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 02:28:10

Generated On: 10 Jun 2021 09:21:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 23:54:37

Generated On: 10 Jun 2021 09:21:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3712032

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 23:54:37

Generated On: 10 Jun 2021 09:21:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 23:54:37

Generated On: 10 Jun 2021 09:21:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3712032

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 23:54:37

Generated On: 10 Jun 2021 09:21:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 23:54:37

Generated On: 10 Jun 2021 09:21:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3712032

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 23:54:37

Generated On: 10 Jun 2021 09:21:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

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

Visit date (dd MMM yyyy)	05 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

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) _____

US3712032

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

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.

US3712032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 APR 2021
Collection time (00:00-23:59)	08:03 (24 HR)
Collection date and time (derived)	05 APR 2021 08:03

US3712032

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712032

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712032

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3712032

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:21:45

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"/>

US3712032

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:21:45

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3712032

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

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 23:54:37

Generated On: 10 Jun 2021 09:21:45

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

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

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

Folder OID	UNBLND_DECIDE
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US3712032

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

Form: Unblinding

Data signed: (b) (4) 04 Apr 2021 23:54:36

Generated On: 10 Jun 2021 09:21:45

Date of updated informed consent (dd MMM yyyy) 22 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 22 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3712032

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 23:54:36

Generated On: 10 Jun 2021 09:21:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 FEB 2021
Collection time (00:00-23:59)	14:30 (24 HR)
Collection date and time (derived)	22 FEB 2021 14:30

US3712032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 04 Apr 2021 23:54:36

Generated On: 10 Jun 2021 09:21:45

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

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

Collection time (00:00 - 23:59)	14:31
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Collection Date and Time (derived)	22 FEB 2021 14:31
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US3712032

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Apr 2021 21:38:27

Generated On: 10 Jun 2021 09:21:45

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 21:38:27

Generated On: 10 Jun 2021 09:21:45

AEID	USA-US068-2021-MRNA-1273-P30 1000014
Adverse event	NON-HODGKIN'S LYMPHOMA
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)	18 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

344 of 2501

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 21:38:27

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 21:38:27

Generated On: 10 Jun 2021 09:21:45

ON 13 MAY 2019, SUBJECT PRESENTED TO ED WITH SHORTNESS OF BREATH AND CT PE STUDY WAS POSITIVE FOR EXTENSIVE PULMONARY EMBOLISM INVOLVING BOTH THE RIGHT AND LEFT PULMONARY ARTERIES. BLE DOPPLER NEGATIVE FOR DVT. SHE RECEIVED THROMBOLYSIS WITH TPA AND HEPARIN FOR 24 HOURS. SHE WAS DISCHARGED HOME ON ANTICOAGULATION WITH ELIQUIS. SUBJECT LOST BUT RE-GAINED INSURANCE AND HAD VISIT TO FOLLOW UP WITH HEMATOLOGIST. SHE STILL HAD RESIDUAL PULMONARY EMBOLI AND A LARGE RETROPERITONEAL MASS. SHE HAD A CT ANGIOGRAM THAT SHOWED AN INCOMPLETELY EVALUATED MIDABDOMINAL RETROPERITONEAL MASS WITH PROBABLE HYDRO-NEPHROSIS OF RIGHT KIDNEY. THE MASS MEASURES AT LEAST 7.7 X 8.5CM AND EXTENDS TO THE MEDIAL MARGIN OF THE KIDNEY. THE SAME DAY SHE HAD A CT ABDOMEN AND PELVIS WITHOUT CONTRAST THAT

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 21:38:27

Generated On: 10 Jun 2021 09:21:45

SHOWED A CENTRAL AND
RIGHT PARACENTRAL
RETROPERITONEAL
HOMOGENEOUS SOFT TISSUE
MASS THAT BEGINS ON THE
RIGHT SIDE AT MILD T12 AND
EXTENDS TO THE MILD PELVIC
AREA, 11.9X14.3CM, THE MASS
ELEVATES AND ENCASES THE
ABDOMINAL AORTA AS WELL
AS ENCASING AND
OBSTRUCTION THE MID RIGHT
URETER AT L3, L4 LEVEL WITH
MODERATE RIGHT RENAL
HYDRONEPHROSIS. PET/CT
SCAN ON 06 JAN 2020 SHOWED
LARGE RETROPERITONEAL
MASS WITH MULTIPLE
HYPERMETABOLIC AREAS.
BONE MARROW ASPIRATION
AND BIOPSY SHOWED
ATYPICAL LYMPHOID
AGGREGATES. NEGATIVE FOR
LYMPHOMA. CHEST X-RAY ON
04JAN2021 SHOWED THAT
THERE WAS BORDERLINE
CARDIAC ENLARGEMENT
WHICH MAY BE PARTIALLY
ARTIFACTUAL DUE TO
PROMINENT EPICARDIAL FAT
PAD. AFTER ALL OF HER
RESULTS SHE WAS
SCHEDULED TO START
CHEMOTHERAPY. SHE WAS
STARTED ON ELIQUIS 5MG BID,

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 21:38:27

Generated On: 10 Jun 2021 09:21:45

STARTED TREATMENT ON 13
JAN 2021 WITH RITUXIMAB
375MG/M2 ON DAY 1 AND
BENDAMUSTINE 90MG/M2 ON
DAY 1 AND 2 EVERY 28 DAYS,
ALLOPURINOL 300MG X 90
DAYS, ZOFRAN, COMPAZINE,
EMLA CREAM, MAGIC
MOUTHWASH, AND LEVAQUIN.
SHE WILL FOLLOW UP IN ONE
MONTH FOR PHYSICAL EXAM
WITH CBC AND CMP. PET/CT
AFTER 3-4 CYCLES. D.DIMER
4.43. DOES NOT HAVE ANY
FAMILY HISTORY OF
LYMPHOMA.

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)	
--	--

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 21:38:27

Generated On: 10 Jun 2021 09:21:45

AEID

Adverse event

WORSENING OF RIGHT LEG
VARICOSE VEIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

349 of 2501

EAB) (1725)

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 21:38:27

Generated On: 10 Jun 2021 09:21:45

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 21:38:27

Generated On: 10 Jun 2021 09:21:45

AEID	
Adverse event	KIDNEY HYDRONEPHROSIS
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)	18 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 21:38:27

Generated On: 10 Jun 2021 09:21:45

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 21:38:27

Generated On: 10 Jun 2021 09:21:45

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

353 of 2501

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 21:38:27

Generated On: 10 Jun 2021 09:21:45

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Apr 2021 21:38:27

Generated On: 10 Jun 2021 09:21:45

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

Yes ☒

No ☐

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

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

356 of 2501

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

	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 JUN 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"/>

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication TRIAMTERENE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 37

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)

358 of 2501

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

	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"/>

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication CITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

360 of 2501

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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)

362 of 2501

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

	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"/>

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication MAGNESIUM

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

364 of 2501

EAB) (1725)

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

	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 2014	
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"/>

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication ADULT 50+ VITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

366 of 2501

EAB) (1725)

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication BODY ACHES, SORE THROAT,
HEADACHE, AND FATIGUE

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

368 of 2501

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

	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)	08 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	09 OCT 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication SHINGLES VACCINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION HEALTH

Dose per administration 1

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

If dose unit is Other, specify DOSES

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

370 of 2501

EAB) (1725)

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 02 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTIVE HEALTH

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

372 of 2501

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		27 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication CHEMOTHERAPY RITUXIMAB

Prophylaxis Yes ☐
No ☒

Indication NON-HODGKIN'S LYMPHOMA

Dose per administration 375

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)

374 of 2501

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	13 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication NON-HODGKIN'S LYMPHOMA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

376 of 2501

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication ALLOPURINOL

Prophylaxis Yes ☐
No ☒

Indication NON-HODGKIN'S LYMPHOMA

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

378 of 2501

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication VALSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 320

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 2501

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

	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 2021	
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"/>

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication LEVOFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication PORT PLACEMENT

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)

382 of 2501

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	05 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication EMLA CREAM

Prophylaxis Yes ☐
No ☒

Indication CHEMO THERAPY
PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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)

384 of 2501

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

	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 JAN 2021
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"/>

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication PROCHLORPERAZINE
MALEATE

Prophylaxis Yes ☐
No ☒

Indication NON-HODGKIN'S LYMPHOMA

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)

386 of 2501

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

	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 JAN 2021
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"/>

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication BENDAMUSTINE

Prophylaxis Yes ☐
No ☒

Indication NON-HODGKIN'S LYMPHOMA

Dose per administration 90

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 28 DAYS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

388 of 2501

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication MAGIC MOUTHWASH (30 ML OF
NYSTATIN, 60 ML
HYDROCORTISONE,
DIPHENHYDRAMINE HCL
100MG)

Prophylaxis Yes ☐
No ☒

Indication NON-HODGKIN'S LYMPHOMA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

390 of 2501

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication RITUXIMAB

Prophylaxis Yes ☐
No ☒

Indication CHEMOTHERAPY
NON-HODGKIN'S LYMPHOMA

Dose per administration 375

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)

392 of 2501

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

	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)		11 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

Name of Medication BENDAMUSTINE

Prophylaxis Yes ☐
No ☒

Indication NON-HODGKIN'S LYMPHOMA

Dose per administration 90

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 2501

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 12 Apr 2021 01:09:30

Generated On: 10 Jun 2021 09:21:45

	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 checked="" 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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	14 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Apr 2021 21:38:27

Generated On: 10 Jun 2021 09:21:45

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:21:45

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
02 NOV 2020	RIGHT LEG VEIN ABLATION	Adverse Event	
06 JAN 2021	PET CT	Adverse Event	
15 DEC 2020	CT ABDOMEN/PELVIS	Adverse Event	
18 DEC 2020	US LOWER EXTREMITIES	Adverse Event	
04 JAN 2021	PORT PLACEMENT	Adverse Event	
18 DEC 2020	RETROPERITONEAL NEEDLE BIOPSY	Adverse Event	
04 JAN 2021	CHEST XRAY	Adverse Event	
20 JAN 2021	BONE MARROW ASPIRATION AND BIOPSY	Adverse Event	

US3712032

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:21:45

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

US3712032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:21:45

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 ☐

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 21:38:28

Generated On: 10 Jun 2021 09:21:45

SAEID	USA-US068-2021-MRNA-1273-P301000014
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	6

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 21:38:28

Generated On: 10 Jun 2021 09:21:45

SAEID	USA-US068-2021-MRNA-1273-P301000014
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	18/FEB/2021 14:52
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

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 21:38:28

Generated On: 10 Jun 2021 09:21:45

SAEID	USA-US068-2021-MRNA-1273-P301000014
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	24/FEB/2021 16:50
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

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Apr 2021 21:38:28

Generated On: 10 Jun 2021 09:21:45

SAEID	USA-US068-2021-MRNA-1273-P301000014
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	25/MAR/2021 14:34
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

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Apr 2021 21:38:28

Generated On: 10 Jun 2021 09:21:45

SAEID	USA-US068-2021-MRNA-1273-P301000014
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	13/APR/2021 06:21
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

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Apr 2021 21:38:28

Generated On: 10 Jun 2021 09:21:45

SAEID	USA-US068-2021-MRNA-1273-P301000014
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	19/APR/2021 08:43
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

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (6)

Data signed: (b) (4) 23 Apr 2021 21:38:28

Generated On: 10 Jun 2021 09:21:45

SAEID	USA-US068-2021-MRNA-1273-P301000014
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	23/APR/2021 13:27
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

US3712032 (Prod: Alliance for Multispecialty Research, LLC)

US3712032

Form: Participant Creation

Generated On: 10 Jun 2021 09:21:45

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered 'US3712032'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:09:35

US3712032

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:29:25

US3712032

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:09:36

US3712032

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

[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 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:29:25

US3712032

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'SCRN'	System	02 Sep 2020 20:29:25

US3712032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:45

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered (b) (6) 1956'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:09:36

US3712032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:45

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '64'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:32:33

US3712032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:45

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'YEARS'	System	02 Sep 2020 20:32:33

US3712032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:45

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '64'	System	02 Sep 2020 20:32:46

US3712032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:45

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:32:33

US3712032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:45

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:32:33

US3712032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:45

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:32:33

US3712032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:45

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:32:33

US3712032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:45

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:32:33

US3712032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:45

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:32:33

US3712032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:45

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:32:33

US3712032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:32:33

US3712032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:45

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:32:33

US3712032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:45

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:32:33

US3712032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:45

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:32:33

US3712032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:32:46

US3712032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Sep 2020'	System	02 Sep 2020 20:32:46

US3712032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2020'	System	02 Sep 2020 20:32:46

US3712032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:45

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:32:46

US3712032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	10 Sep 2020 16:51:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	04 Sep 2020 09:54:37
Query 'Data is required. Please complete.' answered with 'pending randomization' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 20:32:54
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 20:32:46
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:32:46

US3712032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:45

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:32:46

US3712032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:45

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:32:46

US3712032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:45

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:32:46

US3712032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:45

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:09:36

US3712032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:45

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'I'	System	10 Sep 2020 16:51:17

US3712032

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:51:17

US3712032

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:21:45

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User closed query 'During medical record review from the SAE, it was noted in which subject had a pulmonary embolism in May 2019. However, this is not listed in medical history. Please review and confirm as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:40:55
Query 'During medical record review from the SAE, it was noted in which subject had a pulmonary embolism in May 2019. However, this is not listed in medical history. Please review and confirm as needed.' answered with 'has been added ' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 22:26:21
User opened query 'During medical record review from the SAE, it was noted in which subject had a pulmonary embolism in May 2019. However, this is not listed in medical history. Please review and confirm as needed.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 20:02:07
User closed query 'Subject had a vein ablation procedure performed, but varicose veins are not noted in medical history. please confirm reason for this procedure. ' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 20:00:31
Query 'Subject had a vein ablation procedure performed, but varicose veins are not noted in medical history. please confirm reason for this procedure. ' answered with 'added to medical history ' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 20:03:53
User opened query 'Subject had a vein ablation procedure performed, but varicose veins are not noted in medical history. please confirm reason for this procedure. ' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 23:38:28
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:34:33

US3712032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
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)	11 Sep 2020 17:36:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:36:43
Data point term sent to Coder	System	11 Sep 2020 17:35:26
User entered 'allergy to penicillin'	(b) (4), (b) (6)	11 Sep 2020 17:35:16

US3712032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un UNK 1980'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:16

US3712032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:16

US3712032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:16

US3712032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
Signature has been broken.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:14:10
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
Signature has been broken.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:54:22
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:16

US3712032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
Signature has been broken.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:17:19
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:16

US3712032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 1980'	System	11 Sep 2020 17:35:16

US3712032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '1980'	System	11 Sep 2020 17:35:16

US3712032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	11 Sep 2020 17:35:16

US3712032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	11 Sep 2020 17:35:16

US3712032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:36:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:36:42
Data point term sent to Coder	System	11 Sep 2020 17:35:27
User entered 'myopia'	(b) (4), (b) (6)	11 Sep 2020 17:35:26

US3712032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:26

US3712032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:26

US3712032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:26

US3712032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:26

US3712032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:26

US3712032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 1990'	System	11 Sep 2020 17:35:26

US3712032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '1990'	System	11 Sep 2020 17:35:26

US3712032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	11 Sep 2020 17:35:26

US3712032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	11 Sep 2020 17:35:26

US3712032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:37:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:37:37
Data point term sent to Coder	System	11 Sep 2020 17:36:29
User entered 'eczema'	(b) (4), (b) (6)	11 Sep 2020 17:35:43

US3712032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un Mar 2019'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:43

US3712032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:43

US3712032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:43

US3712032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:43

US3712032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:43

US3712032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Mar 2019'	System	11 Sep 2020 17:35:43

US3712032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2019'	System	11 Sep 2020 17:35:43

US3712032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	11 Sep 2020 17:35:43

US3712032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	11 Sep 2020 17:35:43

US3712032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
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)	11 Sep 2020 17:37:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:37:36
Data point term sent to Coder	System	11 Sep 2020 17:36:32
User entered 'hypertension'	(b) (4), (b) (6)	11 Sep 2020 17:35:55

US3712032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:55

US3712032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:55

US3712032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:55

US3712032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:55

US3712032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:55

US3712032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 2000'	System	11 Sep 2020 17:35:55

US3712032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2000'	System	11 Sep 2020 17:35:55

US3712032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	11 Sep 2020 17:35:55

US3712032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	11 Sep 2020 17:35:55

US3712032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 10:24:02
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'data updated ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 18:09:50
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 20:25:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Respiratory tract therapeutic procedures, HLT: Chest wall and mediastinal therapeutic procedures, PT: Chest tube insertion, LLT: Thoracostomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:38:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:38:41
Data point term sent to Coder	System	11 Sep 2020 17:37:36
User entered 'thoracostomy'	(b) (4), (b) (6)	11 Sep 2020 17:36:52

US3712032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un May 2019'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:36:52

US3712032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:36:52

US3712032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:36:52

US3712032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un May 2019'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:36:52

US3712032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:36:52

US3712032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'May 2019'	System	11 Sep 2020 17:36:52

US3712032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2019'	System	11 Sep 2020 17:36:52

US3712032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'May 2019'	System	11 Sep 2020 17:36:52

US3712032

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2019'	System	11 Sep 2020 17:36:52

US3712032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:38:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:38:41
Data point term sent to Coder	System	11 Sep 2020 17:37:37
User entered 'hyperlipidemia'	(b) (4), (b) (6)	11 Sep 2020 17:37:06

US3712032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:37:06

US3712032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:37:06

US3712032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:37:06

US3712032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:37:06

US3712032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:37:06

US3712032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 2000'	System	11 Sep 2020 17:37:06

US3712032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2000'	System	11 Sep 2020 17:37:06

US3712032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	11 Sep 2020 17:37:06

US3712032

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	11 Sep 2020 17:37:06

US3712032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:38:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:38:41
Data point term sent to Coder	System	11 Sep 2020 17:37:37
User entered 'cholecystitis'	(b) (4), (b) (6)	11 Sep 2020 17:37:34

US3712032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un UNK 1985'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:37:34

US3712032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:37:34

US3712032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:37:34

US3712032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un UNK 1985'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:37:34

US3712032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:37:34

US3712032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 1985'	System	11 Sep 2020 17:37:34

US3712032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '1985'	System	11 Sep 2020 17:37:34

US3712032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 1985'	System	11 Sep 2020 17:37:34

US3712032

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '1985'	System	11 Sep 2020 17:37:34

US3712032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:40:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:40:29
Data point term sent to Coder	System	11 Sep 2020 17:38:38
User entered 'cholecystectomy'	(b) (4), (b) (6)	11 Sep 2020 17:37:53

US3712032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un UNK 1985'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:37:53

US3712032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:37:53

US3712032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:37:53

US3712032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un UNK 1985'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:37:53

US3712032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:37:53

US3712032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 1985'	System	11 Sep 2020 17:37:53

US3712032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '1985'	System	11 Sep 2020 17:37:53

US3712032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 1985'	System	11 Sep 2020 17:37:53

US3712032

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '1985'	System	11 Sep 2020 17:37:53

US3712032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Umbilical hernia repair, LLT: Umbilical hernia repair - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:40:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:40:36
Data point term sent to Coder	System	11 Sep 2020 17:38:45
User entered 'umbilical hernia repair'	(b) (4), (b) (6)	11 Sep 2020 17:38:22

US3712032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un Sep 2019'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:38:22

US3712032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:38:22

US3712032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:38:22

US3712032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un Sep 2019'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:38:22

US3712032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:38:22

US3712032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Sep 2019'	System	11 Sep 2020 17:38:22

US3712032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2019'	System	11 Sep 2020 17:38:22

US3712032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Sep 2019'	System	11 Sep 2020 17:38:22

US3712032

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2019'	System	11 Sep 2020 17:38:22

US3712032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:40:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:40:47
Data point term sent to Coder	System	11 Sep 2020 17:40:18
User entered 'bilateral tubal ligation'	(b) (4), (b) (6)	11 Sep 2020 17:40:10

US3712032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un UNK 1978'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:40:10

US3712032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:40:10

US3712032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:40:10

US3712032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un UNK 1978'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:40:10

US3712032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:40:10

US3712032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 1978'	System	11 Sep 2020 17:40:10

US3712032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '1978'	System	11 Sep 2020 17:40:10

US3712032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 1978'	System	11 Sep 2020 17:40:10

US3712032

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '1978'	System	11 Sep 2020 17:40:10

US3712032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 10:24:19
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'data updated ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 18:57:42
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 20:25:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 04:41:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 04:41:45
Data point term sent to Coder	System	11 Sep 2020 17:43:28
User entered 'partial left hip replacement'	(b) (4), (b) (6)	11 Sep 2020 17:42:37

US3712032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un UNK 2009'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:42:37

US3712032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:42:37

US3712032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:42:37

US3712032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un UNK 2009'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:42:37

US3712032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:42:37

US3712032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 2009'	System	11 Sep 2020 17:42:37

US3712032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2009'	System	11 Sep 2020 17:42:37

US3712032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 2009'	System	11 Sep 2020 17:42:37

US3712032

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2009'	System	11 Sep 2020 17:42:37

US3712032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:44:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:44:44
Data point term sent to Coder	System	11 Sep 2020 17:43:28
User entered 'depression'	(b) (4), (b) (6)	11 Sep 2020 17:42:51

US3712032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:42:51

US3712032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:42:51

US3712032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:42:51

US3712032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:42:51

US3712032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:42:51

US3712032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 2005'	System	11 Sep 2020 17:42:51

US3712032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2005'	System	11 Sep 2020 17:42:51

US3712032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	11 Sep 2020 17:42:51

US3712032

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	11 Sep 2020 17:42:51

US3712032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User coded data point as SOC: Vascular disorders, HLT: Embolism and thrombosis, HLT: Non-site specific embolism and thrombosis, PT: Thrombosis, LLT: Clot blood - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 04:29:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 04:29:30
Data point term sent to Coder	System	19 Oct 2020 17:14:48
User entered 'bilateral blood clots'	(b) (4), (b) (6)	19 Oct 2020 17:14:40

US3712032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'UN May 2019'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:14:40

US3712032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:14:40

US3712032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:14:40

US3712032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'UN May 2019'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:14:40

US3712032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:14:40

US3712032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'May 2019'	System	19 Oct 2020 17:14:40

US3712032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2019'	System	19 Oct 2020 17:14:40

US3712032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'May 2019'	System	19 Oct 2020 17:14:40

US3712032

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2019'	System	19 Oct 2020 17:14:40

US3712032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:21:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 08:30:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 08:30:14
Data point term sent to Coder	System	19 Oct 2020 17:15:52
User entered 'left hip, ball and socket was bone on bone'	(b) (4), (b) (6)	19 Oct 2020 17:15:50

US3712032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'UN UNK 2009'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:15:50

US3712032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:15:50

US3712032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:15:50

US3712032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'UN UNK 2009'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:15:50

US3712032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:15:50

US3712032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 2009'	System	19 Oct 2020 17:15:50

US3712032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2009'	System	19 Oct 2020 17:15:50

US3712032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 2009'	System	19 Oct 2020 17:15:50

US3712032

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2009'	System	19 Oct 2020 17:15:50

US3712032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:10
User coded data point as SOC: Vascular disorders, HLT: Varicose veins NEC, PT: Varicose vein, LLT: Varicose veins - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 10:53:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 10:53:11
Data point term sent to Coder	System	23 Feb 2021 20:06:49
User entered 'varicose veins (bilateral)'	(b) (4), (b) (6)	23 Feb 2021 20:05:50

US3712032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:10
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:50

US3712032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:10
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:50

US3712032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:50

US3712032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:50

US3712032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:10
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:50

US3712032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 2010'	System	23 Feb 2021 20:05:50

US3712032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2010'	System	23 Feb 2021 20:05:50

US3712032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	23 Feb 2021 20:05:50

US3712032

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	23 Feb 2021 20:05:50

US3712032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 21:47:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 21:47:53
Data point term sent to Coder	System	24 Mar 2021 21:46:54
User entered 'obstructive sleep apnea'	(b) (4), (b) (6)	24 Mar 2021 21:46:08

US3712032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:46:08

US3712032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:46:08

US3712032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:46:08

US3712032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:46:08

US3712032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:46:08

US3712032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 2010'	System	24 Mar 2021 21:46:08

US3712032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2010'	System	24 Mar 2021 21:46:08

US3712032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	24 Mar 2021 21:46:08

US3712032

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	24 Mar 2021 21:46:08

US3712032

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:21:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Saddle PE - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:18:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:18:07
User signature succeeded.	William Smith (b) (4) (b) (4)	26 Mar 2021 23:47:10
Data point term sent to Coder	System	24 Mar 2021 21:46:55
User entered 'saddle block pulmonary embolus'	(b) (4), (b) (6)	24 Mar 2021 21:46:51

US3712032

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:46:51

US3712032

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:46:51

US3712032

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:46:51

US3712032

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:46:51

US3712032

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:46:51

US3712032

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 2019'	System	24 Mar 2021 21:46:51

US3712032

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2019'	System	24 Mar 2021 21:46:51

US3712032

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 2019'	System	24 Mar 2021 21:46:51

US3712032

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2019'	System	24 Mar 2021 21:46:51

US3712032

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 21:52:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 21:52:41
Data point term sent to Coder	System	24 Mar 2021 21:52:00
User entered 'inguinal hernia'	(b) (4), (b) (6)	24 Mar 2021 21:51:05

US3712032

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'un Sep 2018'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:51:05

US3712032

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:51:05

US3712032

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:51:05

US3712032

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'un Sep 2018'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:51:05

US3712032

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:51:05

US3712032

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Sep 2018'	System	24 Mar 2021 21:51:05

US3712032

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2018'	System	24 Mar 2021 21:51:05

US3712032

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Sep 2018'	System	24 Mar 2021 21:51:05

US3712032

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2018'	System	24 Mar 2021 21:51:05

US3712032

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 21:52:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 21:52:40
Data point term sent to Coder	System	24 Mar 2021 21:52:00
User entered 'inguinal hernia repair'	(b) (4), (b) (6)	24 Mar 2021 21:51:32

US3712032

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'un Sep 2018'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:51:32

US3712032

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:51:32

US3712032

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:51:32

US3712032

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'un Sep 2018'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:51:32

US3712032

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:51:32

US3712032

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Sep 2018'	System	24 Mar 2021 21:51:32

US3712032

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2018'	System	24 Mar 2021 21:51:32

US3712032

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Sep 2018'	System	24 Mar 2021 21:51:32

US3712032

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2018'	System	24 Mar 2021 21:51:32

US3712032

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Endometrial ablation, LLT: Uterine ablation - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 21:53:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 21:53:41
Data point term sent to Coder	System	24 Mar 2021 21:53:01
User entered 'uterine ablation'	(b) (4), (b) (6)	24 Mar 2021 21:52:09

US3712032

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'un UNK 2001'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:52:09

US3712032

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:52:09

US3712032

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:52:09

US3712032

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'un UNK 2001'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:52:09

US3712032

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:52:09

US3712032

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 2001'	System	24 Mar 2021 21:52:09

US3712032

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2001'	System	24 Mar 2021 21:52:09

US3712032

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 2001'	System	24 Mar 2021 21:52:09

US3712032

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2001'	System	24 Mar 2021 21:52:09

US3712032

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:21:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation and uterine bleeding NEC, PT: Dysmenorrhoea, LLT: Dysmenorrhea - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 21:53:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 21:53:41
Data point term sent to Coder	System	24 Mar 2021 21:53:01
User entered 'dysmenorrhea'	(b) (4), (b) (6)	24 Mar 2021 21:52:41

US3712032

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'un UNK 2001'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:52:41

US3712032

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:52:41

US3712032

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:52:41

US3712032

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'un UNK 2001'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:52:41

US3712032

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:52:41

US3712032

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 2001'	System	24 Mar 2021 21:52:41

US3712032

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2001'	System	24 Mar 2021 21:52:41

US3712032

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 2001'	System	24 Mar 2021 21:52:41

US3712032

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2001'	System	24 Mar 2021 21:52:41

US3712032

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:21:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 22:08:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 22:08:40
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 21:53:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 21:53:41
Data point term sent to Coder	System	24 Mar 2021 21:53:01
User entered 'anxiety'	(b) (4), (b) (6)	24 Mar 2021 21:52:51

US3712032

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:52:51

US3712032

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:52:51

US3712032

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:21:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:52:51

US3712032

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:52:51

US3712032

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:21:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	26 Mar 2021 23:47:10
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:52:51

US3712032

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'Jan 2012'	System	24 Mar 2021 21:52:51

US3712032

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '2012'	System	24 Mar 2021 21:52:51

US3712032

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	24 Mar 2021 21:52:51

US3712032

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	24 Mar 2021 21:52:51

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:05

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:05

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '13:36'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:05

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '02 Sep 2020 13:36'	System	11 Sep 2020 17:33:05

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '157.1' cm	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:05
DataPoint set to visible.	System	10 Sep 2020 16:51:17

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '93.7' lb	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:05
DataPoint set to visible.	System	10 Sep 2020 16:51:17

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '17.25697'	System	11 Sep 2020 17:33:05
DataPoint set to visible.	System	10 Sep 2020 16:51:17

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'kg/m2'	System	11 Sep 2020 17:33:05
DataPoint set to visible.	System	10 Sep 2020 16:51:17

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:05

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:05

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:05

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '73'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:05

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'bpm'	System	11 Sep 2020 17:33:05

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '18'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:05

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'breaths/min'	System	11 Sep 2020 17:33:05

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '125'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:05

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'mmHg'	System	11 Sep 2020 17:33:05

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '68'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:05

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'mmHg'	System	11 Sep 2020 17:33:05

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47

US3712032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47

US3712032

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:16

US3712032

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Sep 2020 18:18:40
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 17:55:02
User entered '02 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 17:33:16

US3712032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:21:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:33

US3712032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:21:45

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:33

US3712032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:21:45

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:33

US3712032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:21:45

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:33

US3712032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'un UNK 1978'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:33

US3712032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:21:45

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:33

US3712032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:33

US3712032

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:21:45

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:33

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

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)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

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)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

[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)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

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)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

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)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

[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)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

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)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

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)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Demand planner, restaurants'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

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)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

[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)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

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)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:34:07

US3712032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:55:02

US3712032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:55:02

US3712032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

[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 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:55:02

US3712032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'VISIT1'	System	11 Sep 2020 17:55:02

US3712032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '10 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:40:13

US3712032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:45

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '112993'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:40:13

US3712032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:45

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:40:13

US3712032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:45

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 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:52:44

US3712032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:45

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 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:52:44

US3712032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:45

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:52:44

US3712032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:45

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:52:44

US3712032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:45

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:52:44

US3712032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:45

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:37:29
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 04:57:08
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:57:07

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:45

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '157.1' cm	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:45

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '93.6' kg	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:45

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '157.1' cm	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:45

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '93.6' kg	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '11:00'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered '10 Sep 2020 11:00'	System	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '73'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'bpm'	System	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '18'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'breaths/min'	System	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '131'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'mmHg'	System	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '77'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'mmHg'	System	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:45

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '157.1' cm	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:45

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '93.6' kg	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '13:18'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered '10 Sep 2020 13:18'	System	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '68'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'bpm'	System	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'breaths/min'	System	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '137'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'mmHg'	System	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '76'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'mmHg'	System	11 Sep 2020 17:56:16

US3712032

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:31

US3712032

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:31

US3712032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:22

US3712032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:22

US3712032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

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 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:22

US3712032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 16:53:22

US3712032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:22

US3712032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '12:48'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:22

US3712032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered '10 Sep 2020 12:48'	System	10 Sep 2020 16:53:22

US3712032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:22

US3712032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'ONCE'	System	10 Sep 2020 16:53:22

US3712032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 16:53:22

US3712032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:46

US3712032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:46

US3712032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '11:15'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:56:46

US3712032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered '10 Sep 2020 11:15'	System	11 Sep 2020 17:56:46

US3712032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:21:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:57:00

US3712032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Sep 2020 17:57:00

US3712032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:57:00

US3712032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:45

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '11:17'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:57:00

US3712032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered '10 Sep 2020 11:17'	System	11 Sep 2020 17:57:00

US3712032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Sep 2020 17:57:00

US3712032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:09:04
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:17:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 20:17:21
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:57:00

US3712032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:09:04
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:17:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 20:17:21
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '11:17'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:57:00

US3712032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered empty.	System	15 Feb 2021 20:17:21
User entered '10 Sep 2020 11:17'	System	11 Sep 2020 17:57:00

US3712032

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:53:51

US3712032

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered '1'	System	10 Sep 2020 16:53:51

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T13:13:31', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '0c8246f3-5978-48de-8a7e-9d3cee870173' User entered 'Yes (Y)'	System	10 Sep 2020 17:14:16
	System	10 Sep 2020 17:14:16

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T13:13:38', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '0c8246f3-5978-48de-8a7e-9d3cee870173' User entered '98.1'	System	10 Sep 2020 17:14:16
	System	10 Sep 2020 17:14:16

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T13:13:56', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '0c8246f3-5978-48de-8a7e-9d3cee870173' User entered 'No (N)'	System	10 Sep 2020 17:14:16
	System	10 Sep 2020 17:14:16

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T13:14:12', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '0c8246f3-5978-48de-8a7e-9d3cee870173' User entered '10 Sep 2020 13:14'	System	10 Sep 2020 17:14:16
	System	10 Sep 2020 17:14:16

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '10 Sep 2020 13:08'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '10 Sep 2020 15:38'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T18:29:19', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4a7b294a-4f1f-4c21-badd-131a0b5de223' User entered 'Yes (Y)'	System	10 Sep 2020 22:29:38
	System	10 Sep 2020 22:29:38

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T18:29:24', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4a7b294a-4f1f-4c21-badd-131a0b5de223' User entered '97.7'	System	10 Sep 2020 22:29:38
	System	10 Sep 2020 22:29:38

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T18:29:29', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4a7b294a-4f1f-4c21-badd-131a0b5de223'	System	10 Sep 2020 22:29:38
User entered 'No (N)'	System	10 Sep 2020 22:29:38

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T18:29:33', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4a7b294a-4f1f-4c21-badd-131a0b5de223' User entered '10 Sep 2020 18:29'	System	10 Sep 2020 22:29:38
	System	10 Sep 2020 22:29:38

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '10 Sep 2020 16:33'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 2'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-11T16:31:57', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7436a55b-25b7-4f05-9c0d-9964be1356be' User entered 'Yes (Y)'	System	11 Sep 2020 20:38:22
	System	11 Sep 2020 20:38:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-11T16:38:11', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7436a55b-25b7-4f05-9c0d-9964be1356be' User entered '97.7'	System	11 Sep 2020 20:38:22
	System	11 Sep 2020 20:38:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-11T16:38:13', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7436a55b-25b7-4f05-9c0d-9964be1356be' User entered 'No (N)'	System	11 Sep 2020 20:38:22
	System	11 Sep 2020 20:38:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-11T16:38:18', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7436a55b-25b7-4f05-9c0d-9964be1356be' User entered '11 Sep 2020 16:38'	System	11 Sep 2020 20:38:22
	System	11 Sep 2020 20:38:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 3'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-12T18:43:18', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5da54c24-0f4f-4cea-89f5-c4ac75a19bec' User entered 'Yes (Y)'	System	12 Sep 2020 22:43:30
	System	12 Sep 2020 22:43:30

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-12T18:43:22', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5da54c24-0f4f-4cea-89f5-c4ac75a19bec' User entered '98.5'	System	12 Sep 2020 22:43:30
	System	12 Sep 2020 22:43:30

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-12T18:43:25', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5da54c24-0f4f-4cea-89f5-c4ac75a19bec'	System	12 Sep 2020 22:43:30
User entered 'No (N)'	System	12 Sep 2020 22:43:30

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-12T18:43:28', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5da54c24-0f4f-4cea-89f5-c4ac75a19bec'	System	12 Sep 2020 22:43:30
User entered '12 Sep 2020 18:43'	System	12 Sep 2020 22:43:30

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 4'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-13T20:30:57', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '103c9b4a-a76f-4229-b391-676a5fbce5ef' User entered 'Yes (Y)'	System	14 Sep 2020 00:31:14
	System	14 Sep 2020 00:31:14

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-13T20:31:01', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '103c9b4a-a76f-4229-b391-676a5fbce5ef' User entered '97.7'	System	14 Sep 2020 00:31:14
	System	14 Sep 2020 00:31:14

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-13T20:31:07', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '103c9b4a-a76f-4229-b391-676a5fbce5ef' User entered 'No (N)'	System	14 Sep 2020 00:31:14
	System	14 Sep 2020 00:31:14

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-13T20:31:12', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '103c9b4a-a76f-4229-b391-676a5fbce5ef' User entered '13 Sep 2020 20:31'	System	14 Sep 2020 00:31:14
	System	14 Sep 2020 00:31:14

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 5'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-14T19:24:04', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '406b8ac3-5079-45dc-9c22-f7d966438397' User entered 'Yes (Y)'	System	14 Sep 2020 23:24:27
	System	14 Sep 2020 23:24:27

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-14T19:24:10', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '406b8ac3-5079-45dc-9c22-f7d966438397' User entered '96.9'	System	14 Sep 2020 23:24:27
	System	14 Sep 2020 23:24:27

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-14T19:24:17', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '406b8ac3-5079-45dc-9c22-f7d966438397'	System	14 Sep 2020 23:24:27
User entered 'No (N)'	System	14 Sep 2020 23:24:27

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-14T19:24:21', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '406b8ac3-5079-45dc-9c22-f7d966438397' User entered '14 Sep 2020 19:24'	System	14 Sep 2020 23:24:27
	System	14 Sep 2020 23:24:27

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 6'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-15T17:07:08', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e1b307c9-3265-4aa6-add9-c1c1619c41fb' User entered 'Yes (Y)'	System	15 Sep 2020 21:07:22
	System	15 Sep 2020 21:07:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-15T17:07:12', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e1b307c9-3265-4aa6-add9-c1c1619c41fb' User entered '97.3'	System	15 Sep 2020 21:07:22
	System	15 Sep 2020 21:07:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-15T17:07:16', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e1b307c9-3265-4aa6-add9-c1c1619c41fb' User entered 'No (N)'	System	15 Sep 2020 21:07:22
	System	15 Sep 2020 21:07:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-15T17:07:19', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e1b307c9-3265-4aa6-add9-c1c1619c41fb' User entered '15 Sep 2020 17:07'	System	15 Sep 2020 21:07:22
	System	15 Sep 2020 21:07:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 7'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-16T17:48:49', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'fe776888-0c76-49db-a9a2-26306b2e08c0' User entered 'Yes (Y)'	System	16 Sep 2020 21:49:04
	System	16 Sep 2020 21:49:04

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-16T17:48:55', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'fe776888-0c76-49db-a9a2-26306b2e08c0' User entered '95.7'	System	16 Sep 2020 21:49:04
	System	16 Sep 2020 21:49:04

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-16T17:48:57', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'fe776888-0c76-49db-a9a2-26306b2e08c0'	System	16 Sep 2020 21:49:04
User entered 'No (N)'	System	16 Sep 2020 21:49:04

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-16T17:49:01', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'fe776888-0c76-49db-a9a2-26306b2e08c0' User entered '16 Sep 2020 17:49'	System	16 Sep 2020 21:49:04
	System	16 Sep 2020 21:49:04

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T13:14:41', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1c90de4a-f43f-456b-b0ab-75ceaaaa887'	System	10 Sep 2020 17:15:03
User entered 'None (1)'	System	10 Sep 2020 17:15:03

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T13:14:45', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1c90de4a-f43f-456b-b0ab-75ceeaaaa887' User entered 'No (N)'	System	10 Sep 2020 17:15:03
	System	10 Sep 2020 17:15:03

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T13:14:48', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1c90de4a-f43f-456b-b0ab-75ceeaaaa887' User entered 'No (N)'	System	10 Sep 2020 17:15:03
	System	10 Sep 2020 17:15:03

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T13:14:53', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1c90de4a-f43f-456b-b0ab-75ceaaaa887'	System	10 Sep 2020 17:15:03
User entered 'None (1)'	System	10 Sep 2020 17:15:03

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T13:14:58', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1c90de4a-f43f-456b-b0ab-75ceaaaa887' User entered '10 Sep 2020 13:14'	System	10 Sep 2020 17:15:03
	System	10 Sep 2020 17:15:03

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '10 Sep 2020 13:08'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '10 Sep 2020 15:38'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T18:29:38', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'bbf7f5b8-df4b-40c5-bae8-9a6effc8d365'	System	10 Sep 2020 22:29:58
User entered 'None (1)'	System	10 Sep 2020 22:29:58

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T18:29:46', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'bbf7f5b8-df4b-40c5-bae8-9a6effc8d365'	System	10 Sep 2020 22:29:58
User entered 'No (N)'	System	10 Sep 2020 22:29:58

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T18:29:49', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'bbf7f5b8-df4b-40c5-bae8-9a6effc8d365'	System	10 Sep 2020 22:29:58
User entered 'No (N)'	System	10 Sep 2020 22:29:58

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T18:29:53', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'bbf7f5b8-df4b-40c5-bae8-9a6effc8d365'	System	10 Sep 2020 22:29:58
User entered 'None (1)'	System	10 Sep 2020 22:29:58

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T18:29:55', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'bbf7f5b8-df4b-40c5-bae8-9a6effc8d365'	System	10 Sep 2020 22:29:58
User entered '10 Sep 2020 18:29'	System	10 Sep 2020 22:29:58

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '10 Sep 2020 16:33'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 2'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-11T16:38:28', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4a860b77-64df-4e9c-a2e4-fa2ea386ed3a' User entered 'None (1)'	System	11 Sep 2020 20:38:46
	System	11 Sep 2020 20:38:46

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-11T16:38:32', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4a860b77-64df-4e9c-a2e4-fa2ea386ed3a' User entered 'No (N)'	System	11 Sep 2020 20:38:46
	System	11 Sep 2020 20:38:46

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-11T16:38:36', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4a860b77-64df-4e9c-a2e4-fa2ea386ed3a' User entered 'No (N)'	System	11 Sep 2020 20:38:46
	System	11 Sep 2020 20:38:46

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-11T16:38:41', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4a860b77-64df-4e9c-a2e4-fa2ea386ed3a' User entered 'None (1)'	System	11 Sep 2020 20:38:46
	System	11 Sep 2020 20:38:46

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-11T16:38:44', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4a860b77-64df-4e9c-a2e4-fa2ea386ed3a' User entered '11 Sep 2020 16:38'	System	11 Sep 2020 20:38:46
	System	11 Sep 2020 20:38:46

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 3'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-12T18:43:38', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e04ac75d-40e5-4384-9718-a4109beadfd0'	System	12 Sep 2020 22:43:52
User entered 'None (1)'	System	12 Sep 2020 22:43:52

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-12T18:43:41', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e04ac75d-40e5-4384-9718-a4109beadfd0' User entered 'No (N)'	System	12 Sep 2020 22:43:52
	System	12 Sep 2020 22:43:52

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-12T18:43:44', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e04ac75d-40e5-4384-9718-a4109beadfd0' User entered 'No (N)'	System	12 Sep 2020 22:43:52
	System	12 Sep 2020 22:43:52

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-12T18:43:47', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e04ac75d-40e5-4384-9718-a4109beadfd0' User entered 'None (1)'	System	12 Sep 2020 22:43:52
	System	12 Sep 2020 22:43:52

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-12T18:43:50', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e04ac75d-40e5-4384-9718-a4109beadfd0' User entered '12 Sep 2020 18:43'	System	12 Sep 2020 22:43:52
	System	12 Sep 2020 22:43:52

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 4'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-13T20:31:18', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '42780050-4c5d-4072-94d2-49e85ad495f6' User entered 'None (1)'	System	14 Sep 2020 00:31:33
	System	14 Sep 2020 00:31:33

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-13T20:31:21', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '42780050-4c5d-4072-94d2-49e85ad495f6'	System	14 Sep 2020 00:31:33
User entered 'No (N)'	System	14 Sep 2020 00:31:33

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-13T20:31:24', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '42780050-4c5d-4072-94d2-49e85ad495f6' User entered 'No (N)'	System	14 Sep 2020 00:31:33
	System	14 Sep 2020 00:31:33

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-13T20:31:27', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '42780050-4c5d-4072-94d2-49e85ad495f6' User entered 'None (1)'	System	14 Sep 2020 00:31:33
	System	14 Sep 2020 00:31:33

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-13T20:31:30', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '42780050-4c5d-4072-94d2-49e85ad495f6' User entered '13 Sep 2020 20:31'	System	14 Sep 2020 00:31:33
	System	14 Sep 2020 00:31:33

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 5'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-14T19:24:26', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4f69a805-a53b-4a76-8765-ae939d7e4839' User entered 'None (1)'	System	14 Sep 2020 23:24:43
	System	14 Sep 2020 23:24:43

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-14T19:24:30', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4f69a805-a53b-4a76-8765-ae939d7e4839' User entered 'No (N)'	System	14 Sep 2020 23:24:43
	System	14 Sep 2020 23:24:43

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-14T19:24:32', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4f69a805-a53b-4a76-8765-ae939d7e4839' User entered 'No (N)'	System	14 Sep 2020 23:24:43
	System	14 Sep 2020 23:24:43

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-14T19:24:36', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4f69a805-a53b-4a76-8765-ae939d7e4839' User entered 'None (1)'	System	14 Sep 2020 23:24:43
	System	14 Sep 2020 23:24:43

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-14T19:24:39', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4f69a805-a53b-4a76-8765-ae939d7e4839' User entered '14 Sep 2020 19:24'	System	14 Sep 2020 23:24:43
	System	14 Sep 2020 23:24:43

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 6'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-15T17:07:27', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'ff5fe6f9-aa3d-4b2c-b9da-66acab08a35d'	System	15 Sep 2020 21:07:47
User entered 'None (1)'	System	15 Sep 2020 21:07:47

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-15T17:07:30', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'ff5fe6f9-aa3d-4b2c-b9da-66acab08a35d' User entered 'No (N)'	System	15 Sep 2020 21:07:47
	System	15 Sep 2020 21:07:47

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-15T17:07:33', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'ff5fe6f9-aa3d-4b2c-b9da-66acab08a35d'	System	15 Sep 2020 21:07:47
User entered 'No (N)'	System	15 Sep 2020 21:07:47

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-15T17:07:36', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'ff5fe6f9-aa3d-4b2c-b9da-66acab08a35d'	System	15 Sep 2020 21:07:47
User entered 'None (1)'	System	15 Sep 2020 21:07:47

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-15T17:07:44', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'ff5fe6f9-aa3d-4b2c-b9da-66acab08a35d' User entered '15 Sep 2020 17:07'	System	15 Sep 2020 21:07:47
	System	15 Sep 2020 21:07:47

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 7'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-16T17:49:04', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '2c504a21-804d-4562-a790-80dc21c929d1' User entered 'None (1)'	System	16 Sep 2020 21:49:23
	System	16 Sep 2020 21:49:23

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-16T17:49:13', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '2c504a21-804d-4562-a790-80dc21c929d1' User entered 'No (N)'	System	16 Sep 2020 21:49:23
	System	16 Sep 2020 21:49:23

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-16T17:49:15', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '2c504a21-804d-4562-a790-80dc21c929d1' User entered 'No (N)'	System	16 Sep 2020 21:49:23
	System	16 Sep 2020 21:49:23

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-16T17:49:19', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '2c504a21-804d-4562-a790-80dc21c929d1' User entered 'None (1)'	System	16 Sep 2020 21:49:23
	System	16 Sep 2020 21:49:23

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-16T17:49:22', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '2c504a21-804d-4562-a790-80dc21c929d1' User entered '16 Sep 2020 17:49'	System	16 Sep 2020 21:49:23
	System	16 Sep 2020 21:49:23

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T13:15:16', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd3dd9bea-295c-4169-9f1e-744b17697ff6' User entered 'None (0)'	System	10 Sep 2020 17:15:39
	System	10 Sep 2020 17:15:39

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T13:15:18', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd3dd9bea-295c-4169-9f1e-744b17697ff6' User entered 'None (0)'	System	10 Sep 2020 17:15:39
	System	10 Sep 2020 17:15:39

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T13:15:20', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd3dd9bea-295c-4169-9f1e-744b17697ff6' User entered 'None (0)'	System	10 Sep 2020 17:15:39
	System	10 Sep 2020 17:15:39

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T13:15:23', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd3dd9bea-295c-4169-9f1e-744b17697ff6' User entered 'None (0)'	System	10 Sep 2020 17:15:39
	System	10 Sep 2020 17:15:39

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T13:15:25', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd3dd9bea-295c-4169-9f1e-744b17697ff6' User entered 'None (0)'	System	10 Sep 2020 17:15:39
	System	10 Sep 2020 17:15:39

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T13:15:27', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd3dd9bea-295c-4169-9f1e-744b17697ff6' User entered 'None (0)'	System	10 Sep 2020 17:15:39
	System	10 Sep 2020 17:15:39

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

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)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T13:15:33', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd3dd9bea-295c-4169-9f1e-744b17697ff6'	System	10 Sep 2020 17:15:39
User entered 'No (N)'	System	10 Sep 2020 17:15:39

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T13:15:37', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd3dd9bea-295c-4169-9f1e-744b17697ff6' User entered '10 Sep 2020 13:15'	System	10 Sep 2020 17:15:39
	System	10 Sep 2020 17:15:39

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '10 Sep 2020 13:08'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '10 Sep 2020 15:38'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T18:30:02', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'c7879ae6-6748-437e-9779-8d4150108d76' User entered 'None (0)'	System	10 Sep 2020 22:30:25
	System	10 Sep 2020 22:30:25

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T18:30:07', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'c7879ae6-6748-437e-9779-8d4150108d76' User entered 'None (0)'	System	10 Sep 2020 22:30:25
	System	10 Sep 2020 22:30:25

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T18:30:10', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'c7879ae6-6748-437e-9779-8d4150108d76' User entered 'None (0)'	System	10 Sep 2020 22:30:25
	System	10 Sep 2020 22:30:25

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T18:30:12', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'c7879ae6-6748-437e-9779-8d4150108d76' User entered 'None (0)'	System	10 Sep 2020 22:30:25
	System	10 Sep 2020 22:30:25

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T18:30:14', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'c7879ae6-6748-437e-9779-8d4150108d76' User entered 'None (0)'	System	10 Sep 2020 22:30:25
	System	10 Sep 2020 22:30:25

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T18:30:17', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'c7879ae6-6748-437e-9779-8d4150108d76' User entered 'None (0)'	System	10 Sep 2020 22:30:25
	System	10 Sep 2020 22:30:25

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T18:30:22', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'c7879ae6-6748-437e-9779-8d4150108d76'	System	10 Sep 2020 22:30:25
User entered 'No (N)'	System	10 Sep 2020 22:30:25

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-10T18:30:24', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'c7879ae6-6748-437e-9779-8d4150108d76' User entered '10 Sep 2020 18:30'	System	10 Sep 2020 22:30:25
	System	10 Sep 2020 22:30:25

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '10 Sep 2020 16:33'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 2'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-11T16:38:52', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4b851554-4497-4ab3-9aee-322b9ae6090b' User entered 'None (0)'	System	11 Sep 2020 20:39:30
	System	11 Sep 2020 20:39:30

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-11T16:38:55', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4b851554-4497-4ab3-9aee-322b9ae6090b' User entered 'None (0)'	System	11 Sep 2020 20:39:30
	System	11 Sep 2020 20:39:30

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-11T16:39:04', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4b851554-4497-4ab3-9aee-322b9ae6090b' User entered 'None (0)'	System	11 Sep 2020 20:39:30
	System	11 Sep 2020 20:39:30

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-11T16:39:10', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4b851554-4497-4ab3-9aee-322b9ae6090b' User entered 'None (0)'	System	11 Sep 2020 20:39:30
	System	11 Sep 2020 20:39:30

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-11T16:39:14', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4b851554-4497-4ab3-9aee-322b9ae6090b' User entered 'None (0)'	System	11 Sep 2020 20:39:30
	System	11 Sep 2020 20:39:30

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-11T16:39:17', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4b851554-4497-4ab3-9aee-322b9ae6090b' User entered 'None (0)'	System	11 Sep 2020 20:39:30
	System	11 Sep 2020 20:39:30

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

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)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-11T16:39:22', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4b851554-4497-4ab3-9aee-322b9ae6090b' User entered 'No (N)'	System	11 Sep 2020 20:39:30
	System	11 Sep 2020 20:39:30

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-11T16:39:25', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4b851554-4497-4ab3-9aee-322b9ae6090b' User entered '11 Sep 2020 16:39'	System	11 Sep 2020 20:39:30
	System	11 Sep 2020 20:39:30

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 3'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-12T18:43:55', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'cd68d430-0f84-40a4-a5c7-636b978e1736' User entered 'None (0)'	System	12 Sep 2020 22:44:18
	System	12 Sep 2020 22:44:18

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-12T18:43:57', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'cd68d430-0f84-40a4-a5c7-636b978e1736' User entered 'None (0)'	System	12 Sep 2020 22:44:18
	System	12 Sep 2020 22:44:18

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-12T18:44:01', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'cd68d430-0f84-40a4-a5c7-636b978e1736' User entered 'None (0)'	System	12 Sep 2020 22:44:18
	System	12 Sep 2020 22:44:18

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-12T18:44:03', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'cd68d430-0f84-40a4-a5c7-636b978e1736' User entered 'None (0)'	System	12 Sep 2020 22:44:18
	System	12 Sep 2020 22:44:18

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-12T18:44:05', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'cd68d430-0f84-40a4-a5c7-636b978e1736' User entered 'None (0)'	System	12 Sep 2020 22:44:18
	System	12 Sep 2020 22:44:18

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-12T18:44:07', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'cd68d430-0f84-40a4-a5c7-636b978e1736' User entered 'None (0)'	System	12 Sep 2020 22:44:18
	System	12 Sep 2020 22:44:18

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

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)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-12T18:44:11', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'cd68d430-0f84-40a4-a5c7-636b978e1736'	System	12 Sep 2020 22:44:18
User entered 'No (N)'	System	12 Sep 2020 22:44:18

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-12T18:44:14', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'cd68d430-0f84-40a4-a5c7-636b978e1736'	System	12 Sep 2020 22:44:18
User entered '12 Sep 2020 18:44'	System	12 Sep 2020 22:44:18

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 4'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-13T20:31:35', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '0c7ee002-98e7-406a-871a-409739fd51a4'	System	14 Sep 2020 00:31:54
User entered 'None (0)'	System	14 Sep 2020 00:31:54

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-13T20:31:37', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '0c7ee002-98e7-406a-871a-409739fd51a4' User entered 'None (0)'	System	14 Sep 2020 00:31:54
	System	14 Sep 2020 00:31:54

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-13T20:31:39', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '0c7ee002-98e7-406a-871a-409739fd51a4' User entered 'None (0)'	System	14 Sep 2020 00:31:54
	System	14 Sep 2020 00:31:54

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-13T20:31:41', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '0c7ee002-98e7-406a-871a-409739fd51a4' User entered 'None (0)'	System	14 Sep 2020 00:31:54
	System	14 Sep 2020 00:31:54

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-13T20:31:44', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '0c7ee002-98e7-406a-871a-409739fd51a4' User entered 'None (0)'	System	14 Sep 2020 00:31:54
	System	14 Sep 2020 00:31:54

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-13T20:31:46', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '0c7ee002-98e7-406a-871a-409739fd51a4'	System	14 Sep 2020 00:31:54
User entered 'None (0)'	System	14 Sep 2020 00:31:54

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

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)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-13T20:31:49', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '0c7ee002-98e7-406a-871a-409739fd51a4' User entered 'No (N)'	System	14 Sep 2020 00:31:54
	System	14 Sep 2020 00:31:54

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-13T20:31:51', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '0c7ee002-98e7-406a-871a-409739fd51a4' User entered '13 Sep 2020 20:31'	System	14 Sep 2020 00:31:54
	System	14 Sep 2020 00:31:54

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 5'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-14T19:24:43', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'f07e3263-bef3-4c22-8db8-f1f9a5d6bf09' User entered 'None (0)'	System	14 Sep 2020 23:25:08
	System	14 Sep 2020 23:25:08

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-14T19:24:45', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'f07e3263-bef3-4c22-8db8-f1f9a5d6bf09' User entered 'None (0)'	System	14 Sep 2020 23:25:08
	System	14 Sep 2020 23:25:08

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-14T19:24:47', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'f07e3263-bef3-4c22-8db8-f1f9a5d6bf09' User entered 'None (0)'	System	14 Sep 2020 23:25:08
	System	14 Sep 2020 23:25:08

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-14T19:24:50', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'f07e3263-bef3-4c22-8db8-f1f9a5d6bf09' User entered 'None (0)'	System	14 Sep 2020 23:25:08
	System	14 Sep 2020 23:25:08

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-14T19:24:54', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'f07e3263-bef3-4c22-8db8-f1f9a5d6bf09' User entered 'None (0)'	System	14 Sep 2020 23:25:08
	System	14 Sep 2020 23:25:08

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-14T19:24:56', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'f07e3263-bef3-4c22-8db8-f1f9a5d6bf09' User entered 'None (0)'	System	14 Sep 2020 23:25:08
	System	14 Sep 2020 23:25:08

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

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)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-14T19:25:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'f07e3263-bef3-4c22-8db8-f1f9a5d6bf09'	System	14 Sep 2020 23:25:08
User entered 'No (N)'	System	14 Sep 2020 23:25:08

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-14T19:25:03', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'f07e3263-bef3-4c22-8db8-f1f9a5d6bf09'	System	14 Sep 2020 23:25:08
User entered '14 Sep 2020 19:25'	System	14 Sep 2020 23:25:08

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 6'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-15T17:07:54', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'f01a9187-0e44-4b77-8bf0-f282a974ee09' User entered 'None (0)'	System	15 Sep 2020 21:08:18
	System	15 Sep 2020 21:08:18

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-15T17:07:56', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'f01a9187-0e44-4b77-8bf0-f282a974ee09' User entered 'None (0)'	System	15 Sep 2020 21:08:18
	System	15 Sep 2020 21:08:18

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-15T17:07:59', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'f01a9187-0e44-4b77-8bf0-f282a974ee09' User entered 'None (0)'	System	15 Sep 2020 21:08:18
	System	15 Sep 2020 21:08:18

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-15T17:08:01', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'f01a9187-0e44-4b77-8bf0-f282a974ee09' User entered 'None (0)'	System	15 Sep 2020 21:08:18
	System	15 Sep 2020 21:08:18

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-15T17:08:08', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'f01a9187-0e44-4b77-8bf0-f282a974ee09' User entered 'None (0)'	System	15 Sep 2020 21:08:18
	System	15 Sep 2020 21:08:18

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-15T17:08:10', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'f01a9187-0e44-4b77-8bf0-f282a974ee09' User entered 'None (0)'	System	15 Sep 2020 21:08:18
	System	15 Sep 2020 21:08:18

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

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)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-15T17:08:12', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'f01a9187-0e44-4b77-8bf0-f282a974ee09'	System	15 Sep 2020 21:08:18
User entered 'No (N)'	System	15 Sep 2020 21:08:18

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-15T17:08:16', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'f01a9187-0e44-4b77-8bf0-f282a974ee09' User entered '15 Sep 2020 17:08'	System	15 Sep 2020 21:08:18
	System	15 Sep 2020 21:08:18

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 7'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-16T17:49:25', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd81e52c7-cb09-4b73-a952-f8ce7eac1b72' User entered 'None (0)'	System	16 Sep 2020 21:49:41
	System	16 Sep 2020 21:49:41

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-16T17:49:27', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd81e52c7-cb09-4b73-a952-f8ce7eac1b72' User entered 'None (0)'	System	16 Sep 2020 21:49:41
	System	16 Sep 2020 21:49:41

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-16T17:49:29', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd81e52c7-cb09-4b73-a952-f8ce7eac1b72' User entered 'None (0)'	System	16 Sep 2020 21:49:41
	System	16 Sep 2020 21:49:41

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-16T17:49:30', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd81e52c7-cb09-4b73-a952-f8ce7eac1b72' User entered 'None (0)'	System	16 Sep 2020 21:49:41
	System	16 Sep 2020 21:49:41

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-16T17:49:32', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd81e52c7-cb09-4b73-a952-f8ce7eac1b72' User entered 'None (0)'	System	16 Sep 2020 21:49:41
	System	16 Sep 2020 21:49:41

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-16T17:49:34', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd81e52c7-cb09-4b73-a952-f8ce7eac1b72' User entered 'None (0)'	System	16 Sep 2020 21:49:41
	System	16 Sep 2020 21:49:41

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

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)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-16T17:49:36', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd81e52c7-cb09-4b73-a952-f8ce7eac1b72' User entered 'No (N)'	System	16 Sep 2020 21:49:41
	System	16 Sep 2020 21:49:41

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-09-16T17:49:39', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd81e52c7-cb09-4b73-a952-f8ce7eac1b72' User entered '16 Sep 2020 17:49'	System	16 Sep 2020 21:49:41
	System	16 Sep 2020 21:49:41

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 16:53:22

US3712032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:45:49

US3712032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:45:49

US3712032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:45:49

US3712032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:45:49

US3712032

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:46:49

US3712032

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'I'	System	02 Oct 2020 14:46:49

US3712032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:46:59

US3712032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:46:59

US3712032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:46:59

US3712032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:46:59

US3712032

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:47:22

US3712032

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'I'	System	02 Oct 2020 14:47:22

US3712032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:39:37

US3712032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:39:37

US3712032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:39:37

US3712032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:39:37

US3712032

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:40:17

US3712032

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'I'	System	06 Oct 2020 12:40:17

US3712032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:51:52

US3712032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:51:52

US3712032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

[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 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:51:52

US3712032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered 'VISIT2'	System	07 Oct 2020 14:51:52

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '09:45'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered '07 Oct 2020 09:45'	System	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '37.0' C	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '65'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered 'bpm'	System	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '16'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered 'breaths/min'	System	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '110'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered 'mmHg'	System	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '70'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered 'mmHg'	System	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '11:23'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered '07 Oct 2020 11:23'	System	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '63'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered 'bpm'	System	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '16'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered 'breaths/min'	System	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '133'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered 'mmHg'	System	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '74'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered 'mmHg'	System	07 Oct 2020 15:48:09

US3712032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:12

US3712032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:48:12

US3712032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:52:05

US3712032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:52:05

US3712032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

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 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:52:05

US3712032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 14:52:05

US3712032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:52:05

US3712032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '10:48'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:52:05

US3712032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered '07 Oct 2020 10:48'	System	07 Oct 2020 14:52:05

US3712032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:52:05

US3712032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered 'ONCE'	System	07 Oct 2020 14:52:05

US3712032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 14:52:05

US3712032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:49:26

US3712032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:49:26

US3712032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '09:49'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:49:26

US3712032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered '07 Oct 2020 09:49'	System	07 Oct 2020 15:49:26

US3712032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:21:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:49:43

US3712032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	07 Oct 2020 15:49:43

US3712032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:49:43

US3712032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:45

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '09:53'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:49:43

US3712032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered '07 Oct 2020 09:53'	System	07 Oct 2020 15:49:43

US3712032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	07 Oct 2020 15:49:43

US3712032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:09:04
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:17:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 20:17:30
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:49:43

US3712032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:09:04
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:17:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 20:17:30
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '09:53'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:49:43

US3712032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered empty.	System	15 Feb 2021 20:17:30
User entered '07 Oct 2020 09:53'	System	07 Oct 2020 15:49:43

US3712032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:52:35

US3712032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'I'	System	07 Oct 2020 14:52:35

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T11:23:24', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'c2206528-9bea-4b80-99f1-f60a1391ed34' User entered 'Yes (Y)'	System	07 Oct 2020 15:23:42
	System	07 Oct 2020 15:23:42

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T11:23:30', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'c2206528-9bea-4b80-99f1-f60a1391ed34' User entered '97.9'	System	07 Oct 2020 15:23:42
	System	07 Oct 2020 15:23:42

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T11:23:33', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'c2206528-9bea-4b80-99f1-f60a1391ed34'	System	07 Oct 2020 15:23:42
User entered 'No (N)'	System	07 Oct 2020 15:23:42

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T11:23:39', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'c2206528-9bea-4b80-99f1-f60a1391ed34' User entered '07 Oct 2020 11:23'	System	07 Oct 2020 15:23:42
	System	07 Oct 2020 15:23:42

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '07 Oct 2020 11:08'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '07 Oct 2020 13:38'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T18:03:20', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '84f06510-3c38-4382-981e-e0a655306125' User entered 'Yes (Y)'	System	07 Oct 2020 22:04:08
	System	07 Oct 2020 22:04:08

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T18:03:55', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '84f06510-3c38-4382-981e-e0a655306125' User entered '96.8'	System	07 Oct 2020 22:04:08
	System	07 Oct 2020 22:04:08

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T18:04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '84f06510-3c38-4382-981e-e0a655306125' User entered 'No (N)'	System	07 Oct 2020 22:04:08
	System	07 Oct 2020 22:04:08

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T18:04:04', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '84f06510-3c38-4382-981e-e0a655306125' User entered '07 Oct 2020 18:04'	System	07 Oct 2020 22:04:08
	System	07 Oct 2020 22:04:08

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '07 Oct 2020 14:33'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 2'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:50:04', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'eb7d475b-4287-467f-9cfe-7defca357d1a' User entered 'Yes (Y)'	System	08 Oct 2020 21:50:28
	System	08 Oct 2020 21:50:28

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:50:10', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'eb7d475b-4287-467f-9cfe-7defca357d1a' User entered '98.7'	System	08 Oct 2020 21:50:28
	System	08 Oct 2020 21:50:28

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:50:15', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'eb7d475b-4287-467f-9cfe-7defca357d1a'	System	08 Oct 2020 21:50:28
User entered 'Yes (Y)'	System	08 Oct 2020 21:50:28

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'added' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 12:51:22
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 13:53:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:50:20', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'eb7d475b-4287-467f-9cfe-7defca357d1a'	System	08 Oct 2020 21:50:28
User entered '1'	System	08 Oct 2020 21:50:28

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:50:20', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'eb7d475b-4287-467f-9cfe-7defca357d1a' User entered '0'	System	08 Oct 2020 21:50:28
	System	08 Oct 2020 21:50:28

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:50:25', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'eb7d475b-4287-467f-9cfe-7defca357d1a' User entered '08 Oct 2020 17:50'	System	08 Oct 2020 21:50:28
	System	08 Oct 2020 21:50:28

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 3'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:08:31', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '40fedadd-4715-4aa6-b0d5-dc1e36142be4' User entered 'Yes (Y)'	System	09 Oct 2020 23:08:56
	System	09 Oct 2020 23:08:56

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:08:36', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '40fedadd-4715-4aa6-b0d5-dc1e36142be4' User entered '97.2'	System	09 Oct 2020 23:08:56
	System	09 Oct 2020 23:08:56

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:08:41', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '40fedadd-4715-4aa6-b0d5-dc1e36142be4'	System	09 Oct 2020 23:08:56
User entered 'Yes (Y)'	System	09 Oct 2020 23:08:56

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'added' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 12:51:33
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 13:54:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:08:49', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '40fedadd-4715-4aa6-b0d5-dc1e36142be4'	System	09 Oct 2020 23:08:56
User entered '1'	System	09 Oct 2020 23:08:56

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:08:49', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '40fedadd-4715-4aa6-b0d5-dc1e36142be4' User entered '0'	System	09 Oct 2020 23:08:56
	System	09 Oct 2020 23:08:56

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:08:53', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '40fedadd-4715-4aa6-b0d5-dc1e36142be4' User entered '09 Oct 2020 19:08'	System	09 Oct 2020 23:08:56
	System	09 Oct 2020 23:08:56

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 4'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-10T20:33:13', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '3c2308b9-b882-4dfb-89ba-6e1c22a6b557'	System	11 Oct 2020 00:33:30
User entered 'Yes (Y)'	System	11 Oct 2020 00:33:30

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-10T20:33:19', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '3c2308b9-b882-4dfb-89ba-6e1c22a6b557' User entered '96.8'	System	11 Oct 2020 00:33:30
	System	11 Oct 2020 00:33:30

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-10T20:33:22', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '3c2308b9-b882-4dfb-89ba-6e1c22a6b557'	System	11 Oct 2020 00:33:30
User entered 'No (N)'	System	11 Oct 2020 00:33:30

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-10T20:33:25', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '3c2308b9-b882-4dfb-89ba-6e1c22a6b557' User entered '10 Oct 2020 20:33'	System	11 Oct 2020 00:33:30
	System	11 Oct 2020 00:33:30

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 5'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-11T18:05:17', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'c1279d31-03a5-4792-ba4c-a6486d233357' User entered 'Yes (Y)'	System	11 Oct 2020 22:05:32
	System	11 Oct 2020 22:05:32

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-11T18:05:24', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'c1279d31-03a5-4792-ba4c-a6486d233357' User entered '97.1'	System	11 Oct 2020 22:05:32
	System	11 Oct 2020 22:05:32

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-11T18:05:26', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'c1279d31-03a5-4792-ba4c-a6486d233357'	System	11 Oct 2020 22:05:32
User entered 'No (N)'	System	11 Oct 2020 22:05:32

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-11T18:05:30', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'c1279d31-03a5-4792-ba4c-a6486d233357' User entered '11 Oct 2020 18:05'	System	11 Oct 2020 22:05:32
	System	11 Oct 2020 22:05:32

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 6'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-12T18:49:24', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1fcf158d-12bc-4281-beed-2ae47c8f77cc' User entered 'Yes (Y)'	System	12 Oct 2020 22:49:42
	System	12 Oct 2020 22:49:42

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-12T18:49:36', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1fcf158d-12bc-4281-beed-2ae47c8f77cc' User entered '97.7'	System	12 Oct 2020 22:49:42
	System	12 Oct 2020 22:49:42

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-12T18:49:38', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1fcf158d-12bc-4281-beed-2ae47c8f77cc'	System	12 Oct 2020 22:49:42
User entered 'No (N)'	System	12 Oct 2020 22:49:42

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-12T18:49:41', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1fcf158d-12bc-4281-beed-2ae47c8f77cc' User entered '12 Oct 2020 18:49'	System	12 Oct 2020 22:49:42
	System	12 Oct 2020 22:49:42

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 7'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-14T05:23:11', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd59e39c8-22e8-42fc-b036-08e76ce3c4d9' User entered 'Yes (Y)'	System	14 Oct 2020 09:23:24
	System	14 Oct 2020 09:23:24

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-14T05:23:15', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd59e39c8-22e8-42fc-b036-08e76ce3c4d9' User entered '96.3'	System	14 Oct 2020 09:23:24
	System	14 Oct 2020 09:23:24

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-14T05:23:18', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd59e39c8-22e8-42fc-b036-08e76ce3c4d9' User entered 'No (N)'	System	14 Oct 2020 09:23:24
	System	14 Oct 2020 09:23:24

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-14T05:23:21', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'd59e39c8-22e8-42fc-b036-08e76ce3c4d9' User entered '14 Oct 2020 05:23'	System	14 Oct 2020 09:23:24
	System	14 Oct 2020 09:23:24

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T11:24:26', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'aba234a5-c839-4842-959b-971c2b01c529'	System	07 Oct 2020 15:24:43
User entered 'None (1)'	System	07 Oct 2020 15:24:43

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T11:24:29', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'aba234a5-c839-4842-959b-971c2b01c529' User entered 'No (N)'	System	07 Oct 2020 15:24:43
	System	07 Oct 2020 15:24:43

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T11:24:32', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'aba234a5-c839-4842-959b-971c2b01c529'	System	07 Oct 2020 15:24:43
User entered 'No (N)'	System	07 Oct 2020 15:24:43

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T11:24:35', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'aba234a5-c839-4842-959b-971c2b01c529' User entered 'None (1)'	System	07 Oct 2020 15:24:43
	System	07 Oct 2020 15:24:43

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T11:24:39', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'aba234a5-c839-4842-959b-971c2b01c529' User entered '07 Oct 2020 11:24'	System	07 Oct 2020 15:24:43
	System	07 Oct 2020 15:24:43

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '07 Oct 2020 11:08'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '07 Oct 2020 13:38'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T18:04:09', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'b3492709-e050-489a-a58d-32f046094d32'	System	07 Oct 2020 22:04:40
User entered 'None (1)'	System	07 Oct 2020 22:04:40

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T18:04:12', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'b3492709-e050-489a-a58d-32f046094d32'	System	07 Oct 2020 22:04:40
User entered 'No (N)'	System	07 Oct 2020 22:04:40

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T18:04:14', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'b3492709-e050-489a-a58d-32f046094d32'	System	07 Oct 2020 22:04:40
User entered 'No (N)'	System	07 Oct 2020 22:04:40

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T18:04:33', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'b3492709-e050-489a-a58d-32f046094d32'	System	07 Oct 2020 22:04:40
User entered 'None (1)'	System	07 Oct 2020 22:04:40

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T18:04:37', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'b3492709-e050-489a-a58d-32f046094d32' User entered '07 Oct 2020 18:04'	System	07 Oct 2020 22:04:40
	System	07 Oct 2020 22:04:40

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '07 Oct 2020 14:33'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 2'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:50:35', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'a1bf9d21-1a73-4574-bdb1-97ca9568e42c'	System	08 Oct 2020 21:50:51
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 21:50:51

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:50:38', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'a1bf9d21-1a73-4574-bdb1-97ca9568e42c' User entered 'No (N)'	System	08 Oct 2020 21:50:51
	System	08 Oct 2020 21:50:51

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:50:40', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'a1bf9d21-1a73-4574-bdb1-97ca9568e42c' User entered 'No (N)'	System	08 Oct 2020 21:50:51
	System	08 Oct 2020 21:50:51

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:50:46', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'a1bf9d21-1a73-4574-bdb1-97ca9568e42c'	System	08 Oct 2020 21:50:51
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 21:50:51

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:50:49', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'a1bf9d21-1a73-4574-bdb1-97ca9568e42c' User entered '08 Oct 2020 17:50'	System	08 Oct 2020 21:50:51
	System	08 Oct 2020 21:50:51

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 3'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:09:02', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'cef1bf52-a27f-4535-882c-00f6b4f2dae1' User entered 'None (1)'	System	09 Oct 2020 23:09:32
	System	09 Oct 2020 23:09:32

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:09:13', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'cef1bf52-a27f-4535-882c-00f6b4f2dae1'	System	09 Oct 2020 23:09:32
User entered 'No (N)'	System	09 Oct 2020 23:09:32

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:09:16', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'cef1bf52-a27f-4535-882c-00f6b4f2dae1'	System	09 Oct 2020 23:09:32
User entered 'No (N)'	System	09 Oct 2020 23:09:32

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:09:23', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'cef1bf52-a27f-4535-882c-00f6b4f2dae1' User entered 'None (1)'	System	09 Oct 2020 23:09:32
	System	09 Oct 2020 23:09:32

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:09:30', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'cef1bf52-a27f-4535-882c-00f6b4f2dae1' User entered '09 Oct 2020 19:09'	System	09 Oct 2020 23:09:32
	System	09 Oct 2020 23:09:32

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 4'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-10T20:33:29', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '25f44260-2c00-4c13-a910-d600875fd235'	System	11 Oct 2020 00:33:42
User entered 'None (1)'	System	11 Oct 2020 00:33:42

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-10T20:33:32', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '25f44260-2c00-4c13-a910-d600875fd235' User entered 'No (N)'	System	11 Oct 2020 00:33:42
	System	11 Oct 2020 00:33:42

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-10T20:33:35', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '25f44260-2c00-4c13-a910-d600875fd235'	System	11 Oct 2020 00:33:42
User entered 'No (N)'	System	11 Oct 2020 00:33:42

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-10T20:33:38', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '25f44260-2c00-4c13-a910-d600875fd235'	System	11 Oct 2020 00:33:42
User entered 'None (1)'	System	11 Oct 2020 00:33:42

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-10T20:33:40', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '25f44260-2c00-4c13-a910-d600875fd235' User entered '10 Oct 2020 20:33'	System	11 Oct 2020 00:33:42
	System	11 Oct 2020 00:33:42

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 5'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-11T18:05:34', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '738eebf3-8eb4-4d0a-8dbd-5838454b8e4b' User entered 'None (1)'	System	11 Oct 2020 22:05:48
	System	11 Oct 2020 22:05:48

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-11T18:05:36', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '738eebf3-8eb4-4d0a-8dbd-5838454b8e4b' User entered 'No (N)'	System	11 Oct 2020 22:05:48
	System	11 Oct 2020 22:05:48

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-11T18:05:39', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '738eebf3-8eb4-4d0a-8dbd-5838454b8e4b' User entered 'No (N)'	System	11 Oct 2020 22:05:48
	System	11 Oct 2020 22:05:48

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-11T18:05:43', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '738eebf3-8eb4-4d0a-8dbd-5838454b8e4b' User entered 'None (1)'	System	11 Oct 2020 22:05:48
	System	11 Oct 2020 22:05:48

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-11T18:05:45', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '738eebf3-8eb4-4d0a-8dbd-5838454b8e4b' User entered '11 Oct 2020 18:05'	System	11 Oct 2020 22:05:48
	System	11 Oct 2020 22:05:48

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 6'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-12T18:49:45', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '3fba5851-dab5-42a4-9dda-2f6f63ef2093'	System	12 Oct 2020 22:49:57
User entered 'None (1)'	System	12 Oct 2020 22:49:57

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-12T18:49:48', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '3fba5851-dab5-42a4-9dda-2f6f63ef2093' User entered 'No (N)'	System	12 Oct 2020 22:49:57
	System	12 Oct 2020 22:49:57

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-12T18:49:50', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '3fba5851-dab5-42a4-9dda-2f6f63ef2093'	System	12 Oct 2020 22:49:57
User entered 'No (N)'	System	12 Oct 2020 22:49:57

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-12T18:49:53', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '3fba5851-dab5-42a4-9dda-2f6f63ef2093'	System	12 Oct 2020 22:49:57
User entered 'None (1)'	System	12 Oct 2020 22:49:57

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-12T18:49:55', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '3fba5851-dab5-42a4-9dda-2f6f63ef2093' User entered '12 Oct 2020 18:49'	System	12 Oct 2020 22:49:57
	System	12 Oct 2020 22:49:57

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 7'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-14T05:23:25', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '6c4b0e65-9330-42f7-8bc6-4fe939b4faa6'	System	14 Oct 2020 09:23:43
User entered 'None (1)'	System	14 Oct 2020 09:23:43

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-14T05:23:28', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '6c4b0e65-9330-42f7-8bc6-4fe939b4faa6' User entered 'No (N)'	System	14 Oct 2020 09:23:43
	System	14 Oct 2020 09:23:43

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-14T05:23:31', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '6c4b0e65-9330-42f7-8bc6-4fe939b4faa6'	System	14 Oct 2020 09:23:43
User entered 'No (N)'	System	14 Oct 2020 09:23:43

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-14T05:23:34', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '6c4b0e65-9330-42f7-8bc6-4fe939b4faa6'	System	14 Oct 2020 09:23:43
User entered 'None (1)'	System	14 Oct 2020 09:23:43

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-14T05:23:40', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '6c4b0e65-9330-42f7-8bc6-4fe939b4faa6' User entered '14 Oct 2020 05:23'	System	14 Oct 2020 09:23:43
	System	14 Oct 2020 09:23:43

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T11:24:44', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5d9063fc-0471-46c6-a580-0545804a7c48' User entered 'None (0)'	System	07 Oct 2020 15:25:08
	System	07 Oct 2020 15:25:08

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T11:24:46', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5d9063fc-0471-46c6-a580-0545804a7c48' User entered 'None (0)'	System	07 Oct 2020 15:25:08
	System	07 Oct 2020 15:25:08

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T11:24:49', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5d9063fc-0471-46c6-a580-0545804a7c48' User entered 'None (0)'	System	07 Oct 2020 15:25:08
	System	07 Oct 2020 15:25:08

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T11:24:51', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5d9063fc-0471-46c6-a580-0545804a7c48' User entered 'None (0)'	System	07 Oct 2020 15:25:08
	System	07 Oct 2020 15:25:08

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T11:24:54', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5d9063fc-0471-46c6-a580-0545804a7c48' User entered 'None (0)'	System	07 Oct 2020 15:25:08
	System	07 Oct 2020 15:25:08

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T11:24:56', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5d9063fc-0471-46c6-a580-0545804a7c48' User entered 'None (0)'	System	07 Oct 2020 15:25:08
	System	07 Oct 2020 15:25:08

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

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)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T11:25:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5d9063fc-0471-46c6-a580-0545804a7c48' User entered 'No (N)'	System	07 Oct 2020 15:25:08
	System	07 Oct 2020 15:25:08

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T11:25:02', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5d9063fc-0471-46c6-a580-0545804a7c48' User entered '07 Oct 2020 11:25'	System	07 Oct 2020 15:25:08
	System	07 Oct 2020 15:25:08

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '07 Oct 2020 11:08'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '07 Oct 2020 13:38'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T18:04:45', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '9a864890-3f3b-4144-8552-5cef647d5384' User entered 'None (0)'	System	07 Oct 2020 22:05:09
	System	07 Oct 2020 22:05:09

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T18:04:47', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '9a864890-3f3b-4144-8552-5cef647d5384' User entered 'None (0)'	System	07 Oct 2020 22:05:09
	System	07 Oct 2020 22:05:09

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T18:04:51', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '9a864890-3f3b-4144-8552-5cef647d5384' User entered 'None (0)'	System	07 Oct 2020 22:05:09
	System	07 Oct 2020 22:05:09

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T18:04:53', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '9a864890-3f3b-4144-8552-5cef647d5384' User entered 'None (0)'	System	07 Oct 2020 22:05:09
	System	07 Oct 2020 22:05:09

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T18:04:57', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '9a864890-3f3b-4144-8552-5cef647d5384' User entered 'None (0)'	System	07 Oct 2020 22:05:09
	System	07 Oct 2020 22:05:09

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T18:05:01', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '9a864890-3f3b-4144-8552-5cef647d5384' User entered 'None (0)'	System	07 Oct 2020 22:05:09
	System	07 Oct 2020 22:05:09

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

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)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T18:05:04', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '9a864890-3f3b-4144-8552-5cef647d5384' User entered 'No (N)'	System	07 Oct 2020 22:05:09
	System	07 Oct 2020 22:05:09

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-07T18:05:07', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '9a864890-3f3b-4144-8552-5cef647d5384' User entered '07 Oct 2020 18:05'	System	07 Oct 2020 22:05:09
	System	07 Oct 2020 22:05:09

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '07 Oct 2020 14:33'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 2'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:50:56', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5faffb26-e202-43f0-8bcb-029846079078'	System	08 Oct 2020 21:51:27
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	08 Oct 2020 21:51:27

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:51:01', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5faffb26-e202-43f0-8bcb-029846079078'	System	08 Oct 2020 21:51:27
User entered 'Significant; prevents daily activity (3)'	System	08 Oct 2020 21:51:27

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:51:04', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5faffb26-e202-43f0-8bcb-029846079078'	System	08 Oct 2020 21:51:27
User entered 'Significant; prevents daily activity (3)'	System	08 Oct 2020 21:51:27

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:51:07', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5faffb26-e202-43f0-8bcb-029846079078'	System	08 Oct 2020 21:51:27
User entered 'Significant; prevents daily activity (3)'	System	08 Oct 2020 21:51:27

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:51:10', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5faffb26-e202-43f0-8bcb-029846079078' User entered 'None (0)'	System	08 Oct 2020 21:51:27
	System	08 Oct 2020 21:51:27

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:51:14', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5faffb26-e202-43f0-8bcb-029846079078'	System	08 Oct 2020 21:51:27
User entered 'Prevents daily activity and requires medical attention (3)'	System	08 Oct 2020 21:51:27

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

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)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:51:22', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5faffb26-e202-43f0-8bcb-029846079078'	System	08 Oct 2020 21:51:27
User entered 'No (N)'	System	08 Oct 2020 21:51:27

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-08T17:51:25', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5faffb26-e202-43f0-8bcb-029846079078' User entered '08 Oct 2020 17:51'	System	08 Oct 2020 21:51:27
	System	08 Oct 2020 21:51:27

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 3'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:09:47', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1aa51e3f-0183-49c2-ab98-4bdb8335bb95'	System	09 Oct 2020 23:10:23
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	09 Oct 2020 23:10:23

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:09:52', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1aa51e3f-0183-49c2-ab98-4bdb8335bb95'	System	09 Oct 2020 23:10:23
User entered 'Significant; prevents daily activity (3)'	System	09 Oct 2020 23:10:23

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:09:56', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1aa51e3f-0183-49c2-ab98-4bdb8335bb95'	System	09 Oct 2020 23:10:23
User entered 'Significant; prevents daily activity (3)'	System	09 Oct 2020 23:10:23

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:09:59', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1aa51e3f-0183-49c2-ab98-4bdb8335bb95'	System	09 Oct 2020 23:10:23
User entered 'Significant; prevents daily activity (3)'	System	09 Oct 2020 23:10:23

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:10:03', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1aa51e3f-0183-49c2-ab98-4bdb8335bb95' User entered 'None (0)'	System	09 Oct 2020 23:10:23
	System	09 Oct 2020 23:10:23

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:10:07', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1aa51e3f-0183-49c2-ab98-4bdb8335bb95'	System	09 Oct 2020 23:10:23
User entered 'Prevents daily activity and requires medical attention (3)'	System	09 Oct 2020 23:10:23

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

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)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:10:14', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1aa51e3f-0183-49c2-ab98-4bdb8335bb95' User entered 'No (N)'	System	09 Oct 2020 23:10:23
	System	09 Oct 2020 23:10:23

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-09T19:10:20', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1aa51e3f-0183-49c2-ab98-4bdb8335bb95' User entered '09 Oct 2020 19:10'	System	09 Oct 2020 23:10:23
	System	09 Oct 2020 23:10:23

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 4'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-10T20:33:45', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4ab4a728-1d4a-485b-81f1-f117ba6d5b32' User entered 'None (0)'	System	11 Oct 2020 00:34:07
	System	11 Oct 2020 00:34:07

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-10T20:33:49', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4ab4a728-1d4a-485b-81f1-f117ba6d5b32'	System	11 Oct 2020 00:34:07
User entered 'No interference with activity (1)'	System	11 Oct 2020 00:34:07

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-10T20:33:51', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4ab4a728-1d4a-485b-81f1-f117ba6d5b32' User entered 'None (0)'	System	11 Oct 2020 00:34:07
	System	11 Oct 2020 00:34:07

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-10T20:33:54', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4ab4a728-1d4a-485b-81f1-f117ba6d5b32' User entered 'None (0)'	System	11 Oct 2020 00:34:07
	System	11 Oct 2020 00:34:07

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-10T20:33:56', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4ab4a728-1d4a-485b-81f1-f117ba6d5b32' User entered 'None (0)'	System	11 Oct 2020 00:34:07
	System	11 Oct 2020 00:34:07

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-10T20:33:58', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4ab4a728-1d4a-485b-81f1-f117ba6d5b32' User entered 'None (0)'	System	11 Oct 2020 00:34:07
	System	11 Oct 2020 00:34:07

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

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)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-10T20:34:01', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4ab4a728-1d4a-485b-81f1-f117ba6d5b32'	System	11 Oct 2020 00:34:07
User entered 'No (N)'	System	11 Oct 2020 00:34:07

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-10T20:34:03', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4ab4a728-1d4a-485b-81f1-f117ba6d5b32' User entered '10 Oct 2020 20:34'	System	11 Oct 2020 00:34:07
	System	11 Oct 2020 00:34:07

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 5'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-11T18:05:50', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '2d855265-a050-4595-b227-fc2de5ff1979' User entered 'None (0)'	System	11 Oct 2020 22:06:09
	System	11 Oct 2020 22:06:09

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-11T18:05:52', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '2d855265-a050-4595-b227-fc2de5ff1979' User entered 'None (0)'	System	11 Oct 2020 22:06:09
	System	11 Oct 2020 22:06:09

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-11T18:05:54', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '2d855265-a050-4595-b227-fc2de5ff1979' User entered 'None (0)'	System	11 Oct 2020 22:06:09
	System	11 Oct 2020 22:06:09

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-11T18:05:56', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '2d855265-a050-4595-b227-fc2de5ff1979' User entered 'None (0)'	System	11 Oct 2020 22:06:09
	System	11 Oct 2020 22:06:09

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-11T18:05:58', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '2d855265-a050-4595-b227-fc2de5ff1979' User entered 'None (0)'	System	11 Oct 2020 22:06:09
	System	11 Oct 2020 22:06:09

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-11T18:06:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '2d855265-a050-4595-b227-fc2de5ff1979' User entered 'None (0)'	System	11 Oct 2020 22:06:09
	System	11 Oct 2020 22:06:09

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

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)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-11T18:06:04', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '2d855265-a050-4595-b227-fc2de5ff1979' User entered 'No (N)'	System	11 Oct 2020 22:06:09
	System	11 Oct 2020 22:06:09

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-11T18:06:06', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '2d855265-a050-4595-b227-fc2de5ff1979' User entered '11 Oct 2020 18:06'	System	11 Oct 2020 22:06:09
	System	11 Oct 2020 22:06:09

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 6'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-12T18:49:59', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1cfb0cef-1d0d-4800-a94d-7386ac51fafb' User entered 'None (0)'	System	12 Oct 2020 22:50:16
	System	12 Oct 2020 22:50:16

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-12T18:50:02', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1cfb0cef-1d0d-4800-a94d-7386ac51fafb' User entered 'None (0)'	System	12 Oct 2020 22:50:16
	System	12 Oct 2020 22:50:16

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-12T18:50:04', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1cfb0cef-1d0d-4800-a94d-7386ac51fafb' User entered 'None (0)'	System	12 Oct 2020 22:50:16
	System	12 Oct 2020 22:50:16

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-12T18:50:06', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1cfb0cef-1d0d-4800-a94d-7386ac51fafb' User entered 'None (0)'	System	12 Oct 2020 22:50:16
	System	12 Oct 2020 22:50:16

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-12T18:50:08', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1cfb0cef-1d0d-4800-a94d-7386ac51fafb' User entered 'None (0)'	System	12 Oct 2020 22:50:16
	System	12 Oct 2020 22:50:16

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-12T18:50:10', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1cfb0cef-1d0d-4800-a94d-7386ac51fafb' User entered 'None (0)'	System	12 Oct 2020 22:50:16
	System	12 Oct 2020 22:50:16

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

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)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-12T18:50:12', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1cfb0cef-1d0d-4800-a94d-7386ac51fafb' User entered 'No (N)'	System	12 Oct 2020 22:50:16
	System	12 Oct 2020 22:50:16

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-12T18:50:15', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1cfb0cef-1d0d-4800-a94d-7386ac51fafb' User entered '12 Oct 2020 18:50'	System	12 Oct 2020 22:50:16
	System	12 Oct 2020 22:50:16

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	07 Oct 2020 14:52:05
User entered 'Day 7'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-14T05:23:48', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '387a54ca-3fb0-4f26-8e9b-12cc3b93473b' User entered 'None (0)'	System	14 Oct 2020 09:24:11
	System	14 Oct 2020 09:24:11

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-14T05:23:50', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '387a54ca-3fb0-4f26-8e9b-12cc3b93473b' User entered 'None (0)'	System	14 Oct 2020 09:24:11
	System	14 Oct 2020 09:24:11

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-14T05:23:53', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '387a54ca-3fb0-4f26-8e9b-12cc3b93473b' User entered 'None (0)'	System	14 Oct 2020 09:24:11
	System	14 Oct 2020 09:24:11

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-14T05:23:55', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '387a54ca-3fb0-4f26-8e9b-12cc3b93473b' User entered 'None (0)'	System	14 Oct 2020 09:24:11
	System	14 Oct 2020 09:24:11

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-14T05:23:59', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '387a54ca-3fb0-4f26-8e9b-12cc3b93473b' User entered 'None (0)'	System	14 Oct 2020 09:24:11
	System	14 Oct 2020 09:24:11

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-14T05:24:02', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '387a54ca-3fb0-4f26-8e9b-12cc3b93473b' User entered 'None (0)'	System	14 Oct 2020 09:24:11
	System	14 Oct 2020 09:24:11

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

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)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-14T05:24:04', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '387a54ca-3fb0-4f26-8e9b-12cc3b93473b' User entered 'No (N)'	System	14 Oct 2020 09:24:11
	System	14 Oct 2020 09:24:11

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-10-14T05:24:07', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '387a54ca-3fb0-4f26-8e9b-12cc3b93473b' User entered '14 Oct 2020 05:24'	System	14 Oct 2020 09:24:11
	System	14 Oct 2020 09:24:11

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 14:52:05

US3712032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 14:52:05

US3712032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:58:58

US3712032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:58:58

US3712032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:58:58

US3712032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:58:58

US3712032

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:02:23

US3712032

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'I'	System	28 Oct 2020 15:02:23

US3712032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:02:40

US3712032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:02:40

US3712032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:02:40

US3712032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:02:40

US3712032

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:03:03

US3712032

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'I'	System	28 Oct 2020 15:03:03

US3712032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:05:47

US3712032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:05:47

US3712032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:05:47

US3712032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:05:47

US3712032

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:54:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:05:50

US3712032

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'I'	System	09 Nov 2020 14:05:50

US3712032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:37:31

US3712032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:37:31

US3712032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

[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 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:37:31

US3712032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered 'VISIT3'	System	12 Nov 2020 12:37:31

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:37:40

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:37:40

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:37:40

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered empty.	System	12 Nov 2020 12:37:40

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:37:40

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:37:40

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:37:40

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:37:40

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered empty.	System	12 Nov 2020 12:37:40

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:37:40

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered empty.	System	12 Nov 2020 12:37:40

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:37:40

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered empty.	System	12 Nov 2020 12:37:40

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:37:40

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered empty.	System	12 Nov 2020 12:37:40

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54

US3712032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54

US3712032

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:58:20

US3712032

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 12:58:20

US3712032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 13:05:59

US3712032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 13:05:59

US3712032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered '07:46'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 13:05:59

US3712032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered '04 Nov 2020 07:46'	System	12 Nov 2020 13:05:59

US3712032

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:56:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 13:06:01

US3712032

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:54
User entered 'I'	System	12 Nov 2020 13:06:01

US3712032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 64'	System	10 Sep 2020 16:53:22

US3712032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-11-14T11:59:30', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1449a7b6-b116-4f52-a9b2-f96817b1c137' User entered 'No (N)'	System	14 Nov 2020 16:59:44
	System	14 Nov 2020 16:59:44

US3712032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-11-14T11:59:36', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1449a7b6-b116-4f52-a9b2-f96817b1c137'	System	14 Nov 2020 16:59:44
User entered 'No (N)'	System	14 Nov 2020 16:59:44

US3712032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-11-14T11:59:40', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1449a7b6-b116-4f52-a9b2-f96817b1c137' User entered '14 Nov 2020 11:59:40'	System	14 Nov 2020 16:59:44
	System	14 Nov 2020 16:59:44

US3712032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 16:53:22

US3712032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered 'Day 71'	System	10 Sep 2020 16:53:22

US3712032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-11-19T13:48:40', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e6f239d8-6538-4746-b1d5-d046b875ff59'	System	19 Nov 2020 18:48:55
User entered 'No (N)'	System	19 Nov 2020 18:48:55

US3712032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-11-19T13:48:46', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e6f239d8-6538-4746-b1d5-d046b875ff59'	System	19 Nov 2020 18:48:55
User entered 'No (N)'	System	19 Nov 2020 18:48:55

US3712032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-11-19T13:48:50', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e6f239d8-6538-4746-b1d5-d046b875ff59' User entered '19 Nov 2020 13:48:50'	System	19 Nov 2020 18:48:55
	System	19 Nov 2020 18:48:55

US3712032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered '17 Nov 2020 00:01'	System	10 Sep 2020 16:53:22

US3712032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:53
Data entry locked.	System	10 Sep 2020 16:53:22
User entered '21 Nov 2020 23:59'	System	10 Sep 2020 16:53:22

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-11-30T12:00:47', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e7d5b7fe-7c96-48ea-a1b4-f753aad1f067'	System	30 Nov 2020 17:01:22
User entered 'No (N)'	System	30 Nov 2020 17:01:22

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-11-30T12:00:52', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e7d5b7fe-7c96-48ea-a1b4-f753aad1f067'	System	30 Nov 2020 17:01:22
User entered 'Yes (Y)'	System	30 Nov 2020 17:01:22

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Please 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-11-30T12:00:59', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e7d5b7fe-7c96-48ea-a1b4-f753aad1f067'	System	30 Nov 2020 17:01:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Nov 2020 17:01:22

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-11-30T12:01:04', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e7d5b7fe-7c96-48ea-a1b4-f753aad1f067'	System	30 Nov 2020 17:01:22
User entered '30 Nov 2020 12:01:04'	System	30 Nov 2020 17:01:22

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-12-07T12:00:54', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '44e48074-d61c-4789-ab67-77960bbc252f' User entered 'No (N)'	System	07 Dec 2020 17:01:21
	System	07 Dec 2020 17:01:21

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-12-07T12:00:58', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '44e48074-d61c-4789-ab67-77960bbc252f' User entered 'No (N)'	System	07 Dec 2020 17:01:21

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-12-07T12:01:01', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '44e48074-d61c-4789-ab67-77960bbc252f' User entered '07 Dec 2020 12:01:01'	System	07 Dec 2020 17:01:21
	System	07 Dec 2020 17:01:21

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-12-12T12:31:54', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1c58bd83-cbb3-46cd-b2f2-5af5293e105f' User entered 'No (N)'	System	12 Dec 2020 17:32:04
	System	12 Dec 2020 17:32:04

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-12-12T12:31:57', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1c58bd83-cbb3-46cd-b2f2-5af5293e105f' User entered 'No (N)'	System	12 Dec 2020 17:32:04
	System	12 Dec 2020 17:32:04

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-12-12T12:32:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '1c58bd83-cbb3-46cd-b2f2-5af5293e105f' User entered '12 Dec 2020 12:32:00'	System	12 Dec 2020 17:32:04
	System	12 Dec 2020 17:32:04

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-12-19T12:16:41', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e1ac9ac8-ba43-4cf8-9095-3ac1df6ca8c6' User entered 'No (N)'	System	19 Dec 2020 17:16:52
	System	19 Dec 2020 17:16:52

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-12-19T12:16:47', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e1ac9ac8-ba43-4cf8-9095-3ac1df6ca8c6' User entered 'No (N)'	System	19 Dec 2020 17:16:52

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-12-19T12:16:51', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'e1ac9ac8-ba43-4cf8-9095-3ac1df6ca8c6' User entered '19 Dec 2020 12:16:51'	System	19 Dec 2020 17:16:52
	System	19 Dec 2020 17:16:52

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-12-27T13:36:02', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7fae0c0f-f298-4081-bfc3-d832ce866013' User entered 'Yes (Y)'	System	27 Dec 2020 18:36:32
	System	27 Dec 2020 18:36:32

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-12-27T13:36:05', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7fae0c0f-f298-4081-bfc3-d832ce866013' User entered 'No (N)'	System	27 Dec 2020 18:36:32

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-12-27T13:36:09', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7fae0c0f-f298-4081-bfc3-d832ce866013'	System	27 Dec 2020 18:36:32
User entered 'No (N)'	System	27 Dec 2020 18:36:32

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-12-27T13:36:14', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7fae0c0f-f298-4081-bfc3-d832ce866013'	System	27 Dec 2020 18:36:32
User entered 'Yes (Y)'	System	27 Dec 2020 18:36:32

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Please 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-12-27T13:36:20', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7fae0c0f-f298-4081-bfc3-d832ce866013'	System	27 Dec 2020 18:36:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Dec 2020 18:36:32

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2020-12-27T13:36:24', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7fae0c0f-f298-4081-bfc3-d832ce866013' User entered '27 Dec 2020 13:36:24'	System	27 Dec 2020 18:36:32
	System	27 Dec 2020 18:36:32

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-02T06:48:57', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '079ad560-a1bd-4166-8532-75de66361282'	System	02 Jan 2021 11:49:27
User entered 'Yes (Y)'	System	02 Jan 2021 11:49:27

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-02T06:49:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '079ad560-a1bd-4166-8532-75de66361282'	System	02 Jan 2021 11:49:27
User entered 'No (N)'	System	02 Jan 2021 11:49:27

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-02T06:49:04', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '079ad560-a1bd-4166-8532-75de66361282'	System	02 Jan 2021 11:49:27
User entered 'No (N)'	System	02 Jan 2021 11:49:27

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-02T06:49:11', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '079ad560-a1bd-4166-8532-75de66361282'	System	02 Jan 2021 11:49:27
User entered 'Yes (Y)'	System	02 Jan 2021 11:49:27

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Please 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-02T06:49:15', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '079ad560-a1bd-4166-8532-75de66361282'	System	02 Jan 2021 11:49:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Jan 2021 11:49:27

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-02T06:49:19', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '079ad560-a1bd-4166-8532-75de66361282' User entered '02 Jan 2021 06:49:19'	System	02 Jan 2021 11:49:27
	System	02 Jan 2021 11:49:27

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-09T19:45:18', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7c7ef509-06d5-416a-9aa7-b39d6b98109f' User entered 'Yes (Y)'	System	10 Jan 2021 00:45:49
	System	10 Jan 2021 00:45:49

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-09T19:45:23', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7c7ef509-06d5-416a-9aa7-b39d6b98109f'	System	10 Jan 2021 00:45:49
User entered 'No (N)'	System	10 Jan 2021 00:45:49

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-09T19:45:26', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7c7ef509-06d5-416a-9aa7-b39d6b98109f'	System	10 Jan 2021 00:45:49
User entered 'No (N)'	System	10 Jan 2021 00:45:49

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-09T19:45:30', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7c7ef509-06d5-416a-9aa7-b39d6b98109f'	System	10 Jan 2021 00:45:49
User entered 'Yes (Y)'	System	10 Jan 2021 00:45:49

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Please 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-09T19:45:33', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7c7ef509-06d5-416a-9aa7-b39d6b98109f'	System	10 Jan 2021 00:45:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 00:45:49

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-09T19:45:38', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7c7ef509-06d5-416a-9aa7-b39d6b98109f' User entered '09 Jan 2021 19:45:38'	System	10 Jan 2021 00:45:49
	System	10 Jan 2021 00:45:49

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-18T13:41:39', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '8a7200b9-3ad0-49af-939b-c13f877707c5' User entered 'Yes (Y)'	System	18 Jan 2021 18:42:07
	System	18 Jan 2021 18:42:07

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-18T13:41:42', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '8a7200b9-3ad0-49af-939b-c13f877707c5'	System	18 Jan 2021 18:42:07
User entered 'No (N)'	System	18 Jan 2021 18:42:07

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-18T13:41:46', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '8a7200b9-3ad0-49af-939b-c13f877707c5'	System	18 Jan 2021 18:42:07
User entered 'No (N)'	System	18 Jan 2021 18:42:07

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-18T13:41:52', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '8a7200b9-3ad0-49af-939b-c13f877707c5'	System	18 Jan 2021 18:42:07
User entered 'Yes (Y)'	System	18 Jan 2021 18:42:07

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Please 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-18T13:41:55', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '8a7200b9-3ad0-49af-939b-c13f877707c5'	System	18 Jan 2021 18:42:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Jan 2021 18:42:07

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-18T13:41:58', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '8a7200b9-3ad0-49af-939b-c13f877707c5' User entered '18 Jan 2021 13:41:58'	System	18 Jan 2021 18:42:07
	System	18 Jan 2021 18:42:07

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-24T07:04:31', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '42a3a5f7-6462-4cfa-8759-2a5163bbd5e4' User entered 'Yes (Y)'	System	24 Jan 2021 12:05:00
	System	24 Jan 2021 12:05:00

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-24T07:04:35', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '42a3a5f7-6462-4cfa-8759-2a5163bbd5e4'	System	24 Jan 2021 12:05:00
User entered 'No (N)'	System	24 Jan 2021 12:05:00

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-24T07:04:38', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '42a3a5f7-6462-4cfa-8759-2a5163bbd5e4' User entered 'No (N)'	System	24 Jan 2021 12:05:00

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-24T07:04:45', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '42a3a5f7-6462-4cfa-8759-2a5163bbd5e4' User entered 'Yes (Y)'	System	24 Jan 2021 12:05:00
	System	24 Jan 2021 12:05:00

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Please 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-24T07:04:48', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '42a3a5f7-6462-4cfa-8759-2a5163bbd5e4'	System	24 Jan 2021 12:05:00
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Jan 2021 12:05:00

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-01-24T07:04:51', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '42a3a5f7-6462-4cfa-8759-2a5163bbd5e4' User entered '24 Jan 2021 07:04:51'	System	24 Jan 2021 12:05:00
	System	24 Jan 2021 12:05:00

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-01T12:18:10', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'ed15c9b9-a62c-4863-bc5d-63fc7b12bd22' User entered 'Yes (Y)'	System	01 Feb 2021 17:18:45
	System	01 Feb 2021 17:18:45

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-01T12:18:14', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'ed15c9b9-a62c-4863-bc5d-63fc7b12bd22'	System	01 Feb 2021 17:18:45
User entered 'No (N)'	System	01 Feb 2021 17:18:45

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-01T12:18:19', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'ed15c9b9-a62c-4863-bc5d-63fc7b12bd22'	System	01 Feb 2021 17:18:45
User entered 'No (N)'	System	01 Feb 2021 17:18:45

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-01T12:18:24', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'ed15c9b9-a62c-4863-bc5d-63fc7b12bd22'	System	01 Feb 2021 17:18:45
User entered 'Yes (Y)'	System	01 Feb 2021 17:18:45

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Please 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-01T12:18:27', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'ed15c9b9-a62c-4863-bc5d-63fc7b12bd22'	System	01 Feb 2021 17:18:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Feb 2021 17:18:45

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-01T12:18:32', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'ed15c9b9-a62c-4863-bc5d-63fc7b12bd22' User entered '01 Feb 2021 12:18:32'	System	01 Feb 2021 17:18:45
	System	01 Feb 2021 17:18:45

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-08T12:00:45', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '8831c82e-ee43-47cb-ac64-7984f7e49de8' User entered 'Yes (Y)'	System	08 Feb 2021 17:14:15
	System	08 Feb 2021 17:14:15

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-08T12:00:48', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '8831c82e-ee43-47cb-ac64-7984f7e49de8' User entered 'No (N)'	System	08 Feb 2021 17:14:15

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-08T12:00:52', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '8831c82e-ee43-47cb-ac64-7984f7e49de8' User entered 'No (N)'	System	08 Feb 2021 17:14:15
	System	08 Feb 2021 17:14:15

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-08T12:00:56', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '8831c82e-ee43-47cb-ac64-7984f7e49de8' User entered 'Yes (Y)'	System	08 Feb 2021 17:14:15
	System	08 Feb 2021 17:14:15

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Please 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-08T12:00:59', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '8831c82e-ee43-47cb-ac64-7984f7e49de8'	System	08 Feb 2021 17:14:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Feb 2021 17:14:15

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-08T12:01:03', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '8831c82e-ee43-47cb-ac64-7984f7e49de8' User entered '08 Feb 2021 12:01:03'	System	08 Feb 2021 17:14:15
	System	08 Feb 2021 17:14:15

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-13T19:55:20', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5ad54b35-ff43-4978-bb24-f5bdd2a6f25a' User entered 'Yes (Y)'	System	22 Feb 2021 17:05:30
	System	22 Feb 2021 17:05:30

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-13T19:55:23', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5ad54b35-ff43-4978-bb24-f5bdd2a6f25a' User entered 'No (N)'	System	22 Feb 2021 17:05:30
	System	22 Feb 2021 17:05:30

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-13T19:55:29', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5ad54b35-ff43-4978-bb24-f5bdd2a6f25a' User entered 'No (N)'	System	22 Feb 2021 17:05:30
	System	22 Feb 2021 17:05:30

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-13T19:55:33', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5ad54b35-ff43-4978-bb24-f5bdd2a6f25a' User entered 'Yes (Y)'	System	22 Feb 2021 17:05:30
	System	22 Feb 2021 17:05:30

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Please 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-13T19:55:36', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5ad54b35-ff43-4978-bb24-f5bdd2a6f25a'	System	22 Feb 2021 17:05:30
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Feb 2021 17:05:30

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-13T19:55:50', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5ad54b35-ff43-4978-bb24-f5bdd2a6f25a' User entered '13 Feb 2021 19:55:50'	System	22 Feb 2021 17:05:30
	System	22 Feb 2021 17:05:30

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-22T12:00:53', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7b0f2476-cef4-42dd-87d5-6881ed449182'	System	22 Feb 2021 17:05:42
User entered 'Yes (Y)'	System	22 Feb 2021 17:05:42

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-22T12:00:56', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7b0f2476-cef4-42dd-87d5-6881ed449182'	System	22 Feb 2021 17:05:42
User entered 'No (N)'	System	22 Feb 2021 17:05:42

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-22T12:00:59', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7b0f2476-cef4-42dd-87d5-6881ed449182'	System	22 Feb 2021 17:05:42
User entered 'No (N)'	System	22 Feb 2021 17:05:42

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-22T12:01:03', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7b0f2476-cef4-42dd-87d5-6881ed449182'	System	22 Feb 2021 17:05:42
User entered 'Yes (Y)'	System	22 Feb 2021 17:05:42

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Please 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-22T12:01:06', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7b0f2476-cef4-42dd-87d5-6881ed449182'	System	22 Feb 2021 17:05:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Feb 2021 17:05:42

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-02-22T12:01:09', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '7b0f2476-cef4-42dd-87d5-6881ed449182' User entered '22 Feb 2021 12:01:09'	System	22 Feb 2021 17:05:42
	System	22 Feb 2021 17:05:42

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-03-03T10:00:33-05:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '04011908-34d5-4a51-b1f4-f83ef8d1b612'	System	03 Mar 2021 15:00:44
User entered 'No (N)'	System	03 Mar 2021 15:00:44

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-03-03T10:00:36-05:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '04011908-34d5-4a51-b1f4-f83ef8d1b612'	System	03 Mar 2021 15:00:44
User entered 'No (N)'	System	03 Mar 2021 15:00:44

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-03-03T10:00:39-05:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '04011908-34d5-4a51-b1f4-f83ef8d1b612'	System	03 Mar 2021 15:00:44
User entered '03 Mar 2021 10:00:39'	System	03 Mar 2021 15:00:44

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-03-06T13:03:41-05:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '2fcfa811-017b-4a71-ace5-23c254958108'	System	13 Mar 2021 11:18:02
User entered 'No (N)'	System	13 Mar 2021 11:18:02

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-03-06T13:03:46-05:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '2fcfa811-017b-4a71-ace5-23c254958108'	System	13 Mar 2021 11:18:02
User entered 'No (N)'	System	13 Mar 2021 11:18:02

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-03-06T13:03:49-05:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '2fcfa811-017b-4a71-ace5-23c254958108' User entered '06 Mar 2021 13:03:49'	System	13 Mar 2021 11:18:02
	System	13 Mar 2021 11:18:02

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-03-13T06:18:03-05:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5d3b6a67-9b04-4132-9215-2c7baac21e3a'	System	13 Mar 2021 11:18:17
User entered 'No (N)'	System	13 Mar 2021 11:18:17

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-03-13T06:18:09-05:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5d3b6a67-9b04-4132-9215-2c7baac21e3a'	System	13 Mar 2021 11:18:17
User entered 'No (N)'	System	13 Mar 2021 11:18:17

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-03-13T06:18:15-05:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '5d3b6a67-9b04-4132-9215-2c7baac21e3a'	System	13 Mar 2021 11:18:17
User entered '13 Mar 2021 06:18:15'	System	13 Mar 2021 11:18:17

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-03-22T12:04:33-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '290cb132-216e-4b1f-bfe0-a0f00be56c5a'	System	22 Mar 2021 16:14:08
User entered 'No (N)'	System	22 Mar 2021 16:14:08

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-03-22T12:04:36-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '290cb132-216e-4b1f-bfe0-a0f00be56c5a'	System	22 Mar 2021 16:14:08
User entered 'No (N)'	System	22 Mar 2021 16:14:08

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-03-22T12:04:40-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '290cb132-216e-4b1f-bfe0-a0f00be56c5a' User entered '22 Mar 2021 12:04:40'	System	22 Mar 2021 16:14:08
	System	22 Mar 2021 16:14:08

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-03-27T07:59:28-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4d9c5519-19d8-49bb-99af-f6fd2f5af2eb' User entered 'No (N)'	System	27 Mar 2021 11:59:37
	System	27 Mar 2021 11:59:37

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-03-27T07:59:31-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4d9c5519-19d8-49bb-99af-f6fd2f5af2eb'	System	27 Mar 2021 11:59:37
User entered 'No (N)'	System	27 Mar 2021 11:59:37

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-03-27T07:59:35-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '4d9c5519-19d8-49bb-99af-f6fd2f5af2eb' User entered '27 Mar 2021 07:59:35'	System	27 Mar 2021 11:59:37
	System	27 Mar 2021 11:59:37

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-04-03T17:55:18-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'db8bdde4-a9ce-4d22-8ca3-4b9a776415b5'	System	03 Apr 2021 21:55:27
User entered 'No (N)'	System	03 Apr 2021 21:55:27

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-04-03T17:55:22-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'db8bdde4-a9ce-4d22-8ca3-4b9a776415b5'	System	03 Apr 2021 21:55:27
User entered 'No (N)'	System	03 Apr 2021 21:55:27

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-04-03T17:55:25-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'db8bdde4-a9ce-4d22-8ca3-4b9a776415b5'	System	03 Apr 2021 21:55:27
User entered '03 Apr 2021 17:55:25'	System	03 Apr 2021 21:55:27

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-04-12T12:39:58-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '904625db-63bd-44e8-80e9-91c4d9e402d6'	System	12 Apr 2021 16:40:15
User entered 'No (N)'	System	12 Apr 2021 16:40:15

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-04-12T12:40:01-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '904625db-63bd-44e8-80e9-91c4d9e402d6'	System	12 Apr 2021 16:40:15
User entered 'No (N)'	System	12 Apr 2021 16:40:15

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-04-12T12:40:05-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '904625db-63bd-44e8-80e9-91c4d9e402d6'	System	12 Apr 2021 16:40:15
User entered '12 Apr 2021 12:40:05'	System	12 Apr 2021 16:40:15

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-04-17T07:52:15-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '0a9db1bc-a923-47d7-904e-30593e89ae1c' User entered 'No (N)'	System	24 Apr 2021 11:16:57
	System	24 Apr 2021 11:16:57

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-04-17T07:52:18-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '0a9db1bc-a923-47d7-904e-30593e89ae1c' User entered 'No (N)'	System	24 Apr 2021 11:16:57
	System	24 Apr 2021 11:16:57

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-04-17T07:52:24-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '0a9db1bc-a923-47d7-904e-30593e89ae1c' User entered '17 Apr 2021 07:52:24'	System	24 Apr 2021 11:16:57
	System	24 Apr 2021 11:16:57

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-04-24T07:16:59-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '17d99ec4-5737-4034-a8fe-326f6fbd7128'	System	03 May 2021 16:03:00
User entered 'No (N)'	System	03 May 2021 16:03:00

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Have you been exposed to someone with 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 (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-04-24T07:17:03-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '17d99ec4-5737-4034-a8fe-326f6fbd7128'	System	03 May 2021 16:03:00
User entered 'No (N)'	System	03 May 2021 16:03:00

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-04-24T07:17:07-04:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: '17d99ec4-5737-4034-a8fe-326f6fbd7128'	System	03 May 2021 16:03:00
User entered '24 Apr 2021 07:17:07'	System	03 May 2021 16:03:00

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 02:48:25

US3712032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:48:25
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 02:48:25

US3712032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:21:45

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 22:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-03-03T10:00:22-05:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'dd8c709c-da7d-4c94-89b0-b9b034362fa0'	System	03 Mar 2021 15:00:32
User entered 'No (N)'	System	03 Mar 2021 15:00:32

US3712032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:21:45

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AD5EC1CC-37FD-47D7-946A-5707B46D753F)', Time: '2021-03-03T10:00:28-05:00', User OID: 'PatientReportedOutcome (US3712032)', ODM File OID: 'dd8c709c-da7d-4c94-89b0-b9b034362fa0' User entered '03 Mar 2021 10:00:28'	System	03 Mar 2021 15:00:32
	System	03 Mar 2021 15:00:32

US3712032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:55:17

US3712032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:10
User entered '02 Dec 2020'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:55:17

US3712032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:55:17

US3712032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:55:17

US3712032

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:55:37

US3712032

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:54:26
User entered 'I'	System	11 Dec 2020 12:55:37

US3712032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 19:31:34

US3712032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
	(b) (4)	
User entered '05 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 19:31:34

US3712032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Jan 2021 19:31:34

US3712032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 19:31:34

US3712032

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 19:31:37

US3712032

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User entered 'I'	System	25 Jan 2021 19:31:37

US3712032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 22:26:12

US3712032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
	(b) (4)	
User entered '04 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 22:26:12

US3712032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Feb 2021 22:26:12

US3712032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 22:26:12

US3712032

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 22:26:14

US3712032

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User entered 'I'	System	22 Feb 2021 22:26:14

US3712032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 21:03:47

US3712032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
	(b) (4)	
User entered '05 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 21:03:47

US3712032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Mar 2021 21:03:47

US3712032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 21:03:47

US3712032

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 21:03:49

US3712032

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:38
User entered 'I'	System	10 Mar 2021 21:03:49

US3712032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 19:09:48

US3712032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered '05 Apr 2021'	(b) (4), (b) (6)	05 Apr 2021 19:09:48

US3712032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Apr 2021 19:09:48

US3712032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User entered 'VISIT4'	System	05 Apr 2021 19:09:48

US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 19:09:51

US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:09:51

US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:09:51

US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User entered empty.	System	05 Apr 2021 19:09:51

US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:09:51

US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:09:51

US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:09:51

US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:09:51

US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User entered empty.	System	05 Apr 2021 19:09:51

US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:09:51

US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User entered empty.	System	05 Apr 2021 19:09:51

US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:09:51

US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User entered empty.	System	05 Apr 2021 19:09:51

US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:09:51

US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User entered empty.	System	05 Apr 2021 19:09:51

US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13

US3712032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13

US3712032

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 19:10:00

US3712032

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:10:00

US3712032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 19:10:07

US3712032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered '05 Apr 2021'	(b) (4), (b) (6)	05 Apr 2021 19:10:07

US3712032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered '08:03'	(b) (4), (b) (6)	05 Apr 2021 19:10:07

US3712032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User entered '05 Apr 2021 08:03'	System	05 Apr 2021 19:10:07

US3712032

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 19:11:34

US3712032

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:13
User entered '1'	System	05 Apr 2021 19:11:34

US3712032

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

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:19:57

US3712032

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

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:19:57

US3712032

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

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

[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 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:19:57

US3712032

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

Form: Visit Date

Generated On: 10 Jun 2021 09:21:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered 'UNBLND_DECIDE'	System	23 Feb 2021 19:19:57

US3712032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:45

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered '22 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:43:33
User entered '06 Jan 2021'	(b) (4), (b) (6)	23 Feb 2021 19:20:39

US3712032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:45

[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 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:02:47

US3712032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:45

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:20:39

US3712032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:45

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
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 08:02:47

US3712032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:45

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:20:39

US3712032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:45

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:20:39

US3712032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:45

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:20:39

US3712032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:45

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:20:39

US3712032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:45

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:20:39

US3712032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:45

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	23 Feb 2021 19:20:39

US3712032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:45

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered empty.	System	23 Feb 2021 19:20:39

US3712032

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:20:13

US3712032

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:20:13

US3712032

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered '14:30'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:20:13

US3712032

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '22 Feb 2021 14:30'	System	23 Feb 2021 19:20:13

US3712032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:21:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:20:21

US3712032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:21:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:20:21

US3712032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:21:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered '14:31'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:20:21

US3712032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:21:45

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:47
User entered '22 Feb 2021 14:31'	System	23 Feb 2021 19:20:21

US3712032

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:21:45

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:10
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:03:43
User closed query 'Please confirm, as medical records on 15Dec2020 note that subject had Right Nephrosis. Please review and determine if this should be captured as an AE. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 13:03:41
Query 'Please confirm, as medical records on 15Dec2020 note that subject had Right Nephrosis. Please review and determine if this should be captured as an AE. ' answered with 'added' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 22:20:22
User opened query 'Please confirm, as medical records on 15Dec2020 note that subject had Right Nephrosis. Please review and determine if this should be captured as an AE. ' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 21:34:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 15:10:48
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 13:19:15

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:04:02
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:51:29
User entered	System	18 Feb 2021 19:51:25
'USA-US068-2021-mRNA-1273-P301000014'		
User entered 'New'	(b) (4), (b) (6)	18 Feb 2021 19:51:25

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Lymphomas non-Hodgkin's unspecified histology, HLT: Non-Hodgkin's lymphomas NEC, PT: Non-Hodgkin's lymphoma, LLT: Non-Hodgkin's lymphoma - version MedDRA\23.0.	Coder Import (b) (4)	16 Feb 2021 15:13:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Feb 2021 15:13:58
	(b) (4)	
Data point term sent to Coder	System	16 Feb 2021 15:13:08
User entered 'non-hodgkin's lymphoma'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '18 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 17:27:02
User entered '23 Dec 2020'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 13:04:22
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:24:12
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 15:24:05
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' answered with 'changed to not recovered / not resolved ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:56:04
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' answered with 'changed to not recovered / not resolved ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:55:59

PRODUCTION RELEASE (v12.003
EAB) (1725)

1843 of 2501

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:17:34
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:17:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:26:51
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'updated to "recovering/resolving"' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 11:34:37
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Apr 2021 11:34:04
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	23 Apr 2021 11:34:04
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Apr 2021 11:33:27
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 18:36:39
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4)	26 Feb 2021 18:04:02
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
Query 'PV Query: Please confirm severity of the event as life-threatening is selected as the serious criteria. ' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:02:05
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User opened query 'PV Query: Please confirm severity of the event as life-threatening is selected as the serious criteria. ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:17:56
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 17:10:16
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4)	26 Feb 2021 18:04:02
	(b) (4), (b) (6)	
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	18 Feb 2021 17:09:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 17:09:48
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	18 Feb 2021 17:09:37
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 17:09:37
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 17:09:37
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

None

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 17:09:37
User entered '1'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 17:09:37
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:07:17
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' answered with 'PTOCEDURES HAVE BEEN ADDED ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 21:31:13
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 21:27:48
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 21:27:12
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 21:27:12
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 13:42:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 17:09:37
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 13:04:45
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 17:26:46
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'updated to "recovering/resolving"' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 11:35:12
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 11:34:04
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 11:33:27
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 18:36:49
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 13:55:22
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:55:22

PRODUCTION RELEASE (v12.003
EAB) (1725)

1866 of 2501

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

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 21:38:28
	(b) (4)	
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	23 Apr 2021 11:34:04
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	23 Apr 2021 11:33:27
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:09:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'Has been emailed ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 15:53:38
User closed query 'PV Query: Kindly query for any family history of lymphoma ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:41:57
Query 'PV Query: Kindly query for any family history of lymphoma ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 22:12:55
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 22:12:40

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ON 13 MAY 2019, SUBJECT PRESENTED TO ED WITH SHORTNESS OF BREATH AND CT PE STUDY WAS POSITIVE FOR EXTENSIVE PULMONARY EMBOLISM INVOLVING BOTH THE RIGHT AND LEFT PULMONARY ARTERIES. BLE DOPPLER NEGATIVE FOR DVT. SHE RECEIVED THROMBOLYSIS WITH TPA AND HEPARIN FOR 24 HOURS. SHE WAS DISCHARGED HOME ON ANTICOAGULATION WITH ELIQUIS. SUBJECT LOST BUT RE-GAINED INSURANCE AND HAD VISIT TO FOLLOW UP WITH HEMATOLOGIST. SHE STILL HAD RESIDUAL PULMONARY EMBOLI AND A LARGE RETROPERITONEAL MASS. SHE HAD A CT ANGIOGRAM THAT SHOWED AN INCOMPLETELY EVALUATED MIDABDOMINAL RETROPERITONEAL MASS WITH PROBABLE HYDRO-NEPHROSIS OF RIGHT KIDNEY. THE MASS MEASURES AT LEAST 7.7 X 8.5CM AND EXTENDS TO THE MEDIAL MARGIN OF THE KIDNEY. THE SAME DAY SHE HAD A CT ABDOMEN AND PELVIS WITHOUT CONTRAST THAT SHOWED A CENTRAL AND RIGHT PARACENTRAL RETROPERITONEAL HOMOGENEOUS SOFT TISSUE MASS THAT BEGINS ON THE RIGHT SIDE AT MILD T12 AND EXTENDS TO THE MILD PELVIC AREA,11.9X14.3CM, THE MASS ELEVATES AND ENCASES THE ABDOMINAL AORTA AS WELL AS ENCASING AND OBSTRUCTION THE MID RIGHT URETER AT L3,L4 LEVEL WITH MODERATE RIGHT RENAL HYDRONEPHROSIS. PET/CT SCAN ON 06 JAN 2020 SHOWED LARGE RETROPERITONEAL MASS WITH MULTIPLE HYPERMETABOLIC AREAS. BONE MARROW ASPIRATION AND BIOPSY SHOWED ATYPICAL LYMPHOID AGGREGATES. NEGATIVE FOR LYMPHOMA. CHEST X-RAY ON 04JAN2021 SHOWED THAT THERE WAS BORDERLINE CARDIAC	(b) (4), (b) (6)	16 Apr 2021 22:12:40

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Narrative](#)

Audit	User	Time (GMT)
ENLARGEMENT WHICH MAY BE PARTIALLY ARTIFACTUAL DUE TO PROMINENT EPICARDIAL FAT PAD. AFTER ALL OF HER RESULTS SHE WAS SCHEDULED TO START CHEMOTHERAPY. SHE WAS STARTED ON ELIQUIS 5MG BID, STARTED TREATMENT ON 13 JAN 2021 WITH RITUXIMAB 375MG/M2 ON DAY 1 AND BENDAMUSTINE 90MG/M2 ON DAY 1 AND 2 EVERY 28 DAYS, ALLOPURINOL 300MG X 90 DAYS, ZOFRAN, COMPAZINE, EMLA CREAM, MAGIC MOUTHWASH, AND LEVAQUIN. SHE WILL FOLLOW UP IN ONE MONTH FOR PHYSICAL EXAM WITH CBC AND CMP. PET/CT AFTER 3-4 CYCLES.		
D.DIMER 4.43. Does not have any family history of lymphoma.' reason for change: Data Entry Error User closed query 'PV Query: Please confirm if saddle block pulmonary emboli is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:33:43
Query 'PV Query: Please confirm if saddle block pulmonary emboli is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. ' answered with 'added to medical history ' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 21:54:42
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User opened query 'PV Query: Kindly query for any family history of lymphoma ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:23:27
User opened query 'PV Query: Please confirm if saddle block pulmonary emboli is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:23:07
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:19:00

PRODUCTION RELEASE (v12.003
EAB) (1725)

1871 of 2501

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Narrative](#)

Audit	User	Time (GMT)
User entered 'On 13 May 2019, subject presented to ED with shortness of breath and CT PE study was positive for extensive pulmonary embolism involving both the right and left pulmonary arteries. BLE doppler negative for DVT. She received thrombolysis with TPA and heparin for 24 hours. she was discharged home on anticoagulation with Eliquis. Subject lost but re-gained insurance and had visit to follow up with hematologist. she still had residual pulmonary emboli and a large retroperitoneal mass. She had a CT angiogram that showed an incompletely evaluated midabdominal retroperitoneal mass with probable hydro-nephrosis of right kidney. The mass measures at least 7.7 x 8.5cm and extends to the medial margin of the kidney. The same day she had a CT abdomen and pelvis without contrast that showed a central and right paracentral retroperitoneal homogeneous soft tissue mass that begins on the right side at mild T12 and extends to the mild pelvic area, 11.9x14.3cm, the mass elevates and encases the abdominal aorta as well as encasing and obstruction the mid right ureter at L3,L4 level with moderate right renal hydronephrosis. PET/CT scan on 06 JAN 2020 showed large retroperitoneal mass with multiple hypermetabolic areas. Bone marrow aspiration and biopsy showed atypical lymphoid aggregates. Negative for lymphoma. Chest x-ray on 04JAN2021 showed that there was borderline cardiac enlargement which may be partially artifactual due to prominent epicardial fat pad. After all of her results she was scheduled to start Chemotherapy. She was started on Eliquis 5mg BID, started treatment on 13 JAN 2021 with Rituximab 375mg/m2 on day 1 and bendamustine 90mg/m2 on day 1 and 2 every 28 days, Allopurinol 300mg x 90 days, Zofran, Compazine, EMLA cream, magic mouthwash, and Levaquin. She will follow up in one month for physical exam with CBC and CMP. PET/CT after 3-4 cycles. D.dimer 4.43' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 20:44:17

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Feb 2021 17:17:59
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	18 Feb 2021 17:17:59
User entered 'Subject presented to ED in 2019 with shortness of breath and was diagnosed with saddleblock pulmonary emboli. Subject was advised to follow up with further work up, but lost insurance and was unable to complete further testing. When they regained their insurance they returned to oncologist/hematologist and was subsequently diagnosed with Non Hodgkins Lymphoma on 18 DEC 2020.' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 17:17:59
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Feb 2021 17:09:48
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 17:09:48
User entered '0'	System	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Feb 2021 15:12:53

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:39:01
User closed query 'Please confirm if this is a procedure, if procedure, this should only be listed on con procedure page. If varicose veins worsened, then please consider adding an AE. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:39:00
User coded data point as SOC: Vascular disorders, HLGT: Venous varices, HLT: Varicose veins NEC, PT: Varicose vein, LLT: Varicose veins - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 16:20:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 16:20:18
Data point term sent to Coder	System	24 Mar 2021 21:44:50
User closed query 'CDM Coding: Please specify the underlying medical condition for 'RIGHT LEG VEIN ABLATION'.' (Site from System).	System	24 Mar 2021 21:44:13
Query 'CDM Coding: Please specify the underlying medical condition for 'RIGHT LEG VEIN ABLATION'.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 21:44:13
User entered 'WORSENING OF right leg VARICOSE VEIN' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 21:44:01
Data point term sent to Coder	System	24 Mar 2021 21:43:49
Query 'Please confirm if this is a procedure, if procedure, this should only be listed on con procedure page. If varicose veins worsened, then please consider adding an AE. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 21:43:09
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 21:42:56
User entered 'worsening of varicose veins' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 21:42:56
User opened query 'CDM Coding: Please specify the underlying medical condition for 'RIGHT LEG VEIN ABLATION'.' (Site from System).	Coder Import (b) (4) (b) (4)	19 Mar 2021 04:02:53

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Please confirm if this is a procedure, if procedure, this should only be listed on con procedure page. If varicose veins worsened, then please consider adding an AE. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:04:46
	(b) (4), (b) (6)	26 Feb 2021 18:04:02
Data point term sent to Coder	System	16 Feb 2021 15:15:10
User entered 'right leg vein ablation '	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '02 Nov 2020'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered empty.	System	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	16 Feb 2021 15:15:24
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	16 Feb 2021 15:15:24
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	16 Feb 2021 15:14:55
User entered '02 Nov 2020'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered empty.	System	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User closed query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade 1. Please confirm/update the severity. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:34:32
Query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade 1. Please confirm/update the severity. Else, clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 20:28:28
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 20:28:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 20:28:22
User opened query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade 1. Please confirm/update the severity. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 02:48:37
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 15:15:39
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Feb 2021 15:15:24
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 15:15:24
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Feb 2021 15:14:55
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 15:15:39
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 15:15:24
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:04:02
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered '0'	System	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26
User entered '1'	System	16 Feb 2021 15:14:55

US3712032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:26

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal obstructive disorders, PT: Hydronephrosis, LLT: Hydronephrosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Apr 2021 12:01:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 12:01:50
Data point term sent to Coder	System	16 Apr 2021 22:21:01
User entered 'kidney hydronephrosis'	(b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[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 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 22:20:05

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Apr 2021 15:55:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 15:55:39
Data point term sent to Coder	System	19 Apr 2021 15:54:51
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '01 Dec 2020'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

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 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 15:54:28

US3712032

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 15:54:28

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:10
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User closed query 'Please ensure to add each weekly round of chemo for this participant. Please add the following meds: Valsartan, Levofloxacin, EMLA cream, Prochlorperazine Maleate, Bendamustine, Magic Mouthwash, Neulasta Growth Factor Support. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:04:43
Query 'Please ensure to add each weekly round of chemo for this participant. Please add the following meds: Valsartan, Levofloxacin, EMLA cream, Prochlorperazine Maleate, Bendamustine, Magic Mouthwash, Neulasta Growth Factor Support. ' answered with 'medications have been added' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 22:23:54
User opened query 'Please ensure to add each weekly round of chemo for this participant. Please add the following meds: Valsartan, Levofloxacin, EMLA cream, Prochlorperazine Maleate, Bendamustine, Magic Mouthwash, Neulasta Growth Factor Support. ' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 17:26:08
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 17:22:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:43:01

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
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)	11 Sep 2020 17:48:39
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	11 Sep 2020 17:48:39
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	11 Sep 2020 17:47:35
User entered 'atorvastatin'	(b) (4), (b) (6)	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'hyperlipidemia'	(b) (4), (b) (6)	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '80'	(b) (4), (b) (6)	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'un Jun 2019'	(b) (4), (b) (6)	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 17:47:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: OTHER POTASSIUM-SPARING AGENTS, PRODUCT: TRIAMTERENE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:49:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:49:46
Data point term sent to Coder	System	11 Sep 2020 17:48:38
User entered 'triamterene'	(b) (4), (b) (6)	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'hypertension'	(b) (4), (b) (6)	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '37'	(b) (4), (b) (6)	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'un UNK 2000'	(b) (4), (b) (6)	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 17:48:11

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:50:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:50:38
Data point term sent to Coder	System	11 Sep 2020 17:49:39
User entered 'citalopram'	(b) (4), (b) (6)	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'depression'	(b) (4), (b) (6)	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '20'	(b) (4), (b) (6)	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'un UNK 2005'	(b) (4), (b) (6)	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 17:48:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:01:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:01:28
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	14 Oct 2020 18:01:05 14 Oct 2020 18:00:44
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 23:21:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 23:21:40
Data point term sent to Coder User entered 'aspirin'	System (b) (4), (b) (6)	11 Sep 2020 17:50:40 11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	21 Oct 2020 09:30:28
' (Site from DM).		
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	14 Oct 2020 18:00:50
' answered with 'data updated ' (Site from DM).		
User entered 'cardiac PROPHYLAXIS' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 18:00:44
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	08 Oct 2020 08:25:11
' (Site from DM).		
User entered 'prophylaxis prevention'	(b) (4), (b) (6)	11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '81'	(b) (4), (b) (6)	11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'un UNK 2018'	(b) (4), (b) (6)	11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 17:49:45

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:51:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:51:41
Data point term sent to Coder	System	11 Sep 2020 17:50:41
User entered 'magnesium'	(b) (4), (b) (6)	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:41:17
User closed query 'Please confirm as all supplements are considered prophylaxis. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:41:16
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
Query 'Please confirm as all supplements are considered prophylaxis. ' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:59:25
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 21:59:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 21:59:13
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User opened query 'Please confirm as all supplements are considered prophylaxis. ' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 15:31:25
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'supplement'	(b) (4), (b) (6)	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '400'	(b) (4), (b) (6)	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'un UNK 2014'	(b) (4), (b) (6)	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 17:50:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: VITAMINS NOS, PRODUCTS SYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 22:13:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 22:13:45
Data point term sent to Coder	System	11 Sep 2020 17:50:42
User entered 'adult 50+ vitamin'	(b) (4), (b) (6)	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:41:25
User closed query 'Please confirm, as all supplements are considered prophylaxis. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:41:24
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
Query 'Please confirm, as all supplements are considered prophylaxis. ' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:00:03
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 21:59:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 21:59:49
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User opened query 'Please confirm, as all supplements are considered prophylaxis. ' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 15:31:58
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'supplement'	(b) (4), (b) (6)	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'I'	(b) (4), (b) (6)	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:41:34
User closed query 'Please confirm if this is accurate, as this subject is only 64 and 1980 for a 50+ year old vitamin seems inaccurate. Please review and confirm.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:41:33
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
Query 'Please confirm if this is accurate, as this subject is only 64 and 1980 for a 50+ year old vitamin seems inaccurate. Please review and confirm.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 22:02:01
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 22:01:01
User entered 'UN UNK 2010' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 22:01:01
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User opened query 'Please confirm if this is accurate, as this subject is only 64 and 1980 for a 50+ year old vitamin seems inaccurate. Please review and confirm.' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 15:37:40
User entered 'un UNK 1980'	(b) (4), (b) (6)	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:50:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:50:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:50:47
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:50:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:50:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:50:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:50:47
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:50:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 17:50:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 18:32:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 18:32:23
Data point term sent to Coder	System	12 Oct 2020 18:31:18
User entered 'tylenol'	(b) (4), (b) (6)	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User closed query 'Per DM CLR-RQ: Response noted. However, please re-review if AE reporting criteria per protocol 8.3.4 has been met. If yes, update to record indication as adverse event. If no, confirm/enter in query response that "BODY ACHES, SORE THROAT, HEADACHE, AND FATIGUE DID NOT MEET AE REPORTING CRITERIA." Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 02:31:27
Query 'Per DM CLR-RQ: Response noted. However, please re-review if AE reporting criteria per protocol 8.3.4 has been met. If yes, update to record indication as adverse event. If no, confirm/enter in query response that "BODY ACHES, SORE THROAT, HEADACHE, AND FATIGUE DID NOT MEET AE REPORTING CRITERIA." Update as appropriate. Otherwise, clarify.' answered with 'BODY ACHES, SORE THROAT, HEADACHE, AND FATIGUE DOES NOT MEET AE REPORTING CRITERIA ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 22:02:37
User opened query 'Per DM CLR-RQ: Response noted. However, please re-review if AE reporting criteria per protocol 8.3.4 has been met. If yes, update to record indication as adverse event. If no, confirm/enter in query response that "BODY ACHES, SORE THROAT, HEADACHE, AND FATIGUE DID NOT MEET AE REPORTING CRITERIA." Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 01:50:08
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 17:21:41

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the BODY ACHES, SORE THROAT, HEADACHE, AND FATIGUE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of BODY ACHES, SORE THROAT, HEADACHE, AND FATIGUE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 07:08:34
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the BODY ACHES, SORE THROAT, HEADACHE, AND FATIGUE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of BODY ACHES, SORE THROAT, HEADACHE, AND FATIGUE did not meet the AE reporting criteria.' answered with 'was within 7 day diary window, therefore does not need AE' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 17:42:39

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the BODY ACHES, SORE THROAT, HEADACHE, AND FATIGUE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of BODY ACHES, SORE THROAT, HEADACHE, AND FATIGUE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 05:37:35
User entered 'Body aches, sore throat, headache, and fatigue'	(b) (4), (b) (6)	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '650'	(b) (4), (b) (6)	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'as needed (PRN)'	(b) (4), (b) (6)	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '08 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 13:53:24
User entered '08 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 18:57:27
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 17:46:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 17:46:11
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 05:37:49
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:31:13

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User closed query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 07:09:14
Query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' answered with 'Had this vaccine 26 days after their second dose of moderna ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 17:45:43
User opened query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 18:09:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:13:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:13:11
Data point term sent to Coder	System	12 Nov 2020 13:05:22
User entered 'shingles vaccine'	(b) (4), (b) (6)	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'prevention health'	(b) (4), (b) (6)	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Other (OTHER)'	(b) (4), (b) (6)	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'doses '	(b) (4), (b) (6)	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'once (ONCE)'	(b) (4), (b) (6)	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '02 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '02 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 13:04:52

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 13:07:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 13:07:45
Data point term sent to Coder	System	12 Nov 2020 13:06:23
User entered 'influenza vaccine'	(b) (4), (b) (6)	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'preventive health'	(b) (4), (b) (6)	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '0.5'	(b) (4), (b) (6)	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'mL (mL)'	(b) (4), (b) (6)	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'once (ONCE)'	(b) (4), (b) (6)	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '27 Oct 2020'	(b) (4), (b) (6)	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '27 Oct 2020'	(b) (4), (b) (6)	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 13:05:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

Name of Medication

Audit	User	Time (GMT)
User closed query "'Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 '''Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses'''' ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	13 Apr 2021 20:26:38
Query "'Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 '''Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses'''' ' answered with 'epif was done and was told subject should continue ' (Site from DM). User opened query "'Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 '''Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses'''' ' (Site from DM). User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: MONOCLONAL ANTIBODIES, PRODUCT: RITUXIMAB - version WHODrug-Global-B3\\202003. User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. DataPoint Verified.	William Smith (b) (4) (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) Coder Import (b) (4) (b) (4) Coder Import (b) (4) (b) (4) (b) (4), (b) (6)	12 Apr 2021 01:09:31 05 Apr 2021 19:17:28 30 Mar 2021 00:14:57 11 Mar 2021 20:34:08 11 Mar 2021 20:34:08 26 Feb 2021 17:21:41
Data point term sent to Coder	System	23 Feb 2021 19:09:49
User closed query 'For coding purposes, the reported name cannot be referenced in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name and please make your changes to the reported term.' (Site from System).	System	23 Feb 2021 19:09:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'For coding purposes, the reported name cannot be referenced in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name and please make your changes to the reported term.' answered with 'updated ' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 19:09:32
User entered 'chemotherapy rituximab' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 19:08:56
User opened query 'For coding purposes, the reported name cannot be referenced in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name and please make your changes to the reported term.' (Site from System).	Coder Import (b) (4)	16 Feb 2021 17:38:00
Data point term sent to Coder	(b) (4)	
User entered 'chemotherapy'	System	16 Feb 2021 15:20:16
	(b) (4), (b) (6)	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'non-hodgkin's lymphoma'	(b) (4), (b) (6)	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 19:08:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 19:08:56
User entered '375' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 19:08:56
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 15:19:21
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 19:08:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 19:08:56
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 19:08:56
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 15:19:21
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 19:08:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 19:08:56
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 19:08:56
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 15:19:21
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 19:08:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 19:08:56
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 19:08:56
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 15:19:21
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	23 Feb 2021 19:08:56
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 19:08:56
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	16 Feb 2021 15:19:21
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	26 Feb 2021 17:21:41
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 19:08:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 19:08:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 19:08:56
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 15:19:21
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 19:08:56
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 19:08:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 19:08:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 19:08:56
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 15:19:21
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 15:19:21

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 15:21:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 15:21:59
	(b) (4)	
Data point term sent to Coder	System	16 Feb 2021 15:21:17
User entered 'eliquis'	(b) (4), (b) (6)	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'non-hodgkin's lymphoma'	(b) (4), (b) (6)	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '5'	(b) (4), (b) (6)	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'twice daily (BID)'	(b) (4), (b) (6)	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '23 Dec 2020'	(b) (4), (b) (6)	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Feb 2021 15:20:42

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 17:20:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 17:20:59
Data point term sent to Coder	System	16 Feb 2021 15:22:18
User entered 'allopurinol'	(b) (4), (b) (6)	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'non-hodgkin's lymphoma'	(b) (4), (b) (6)	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '300'	(b) (4), (b) (6)	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '23 Dec 2020'	(b) (4), (b) (6)	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 17:21:41
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Feb 2021 15:21:25

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of HYPERTENSION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 20:26:49
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of HYPERTENSION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' answered with 'hypertension did not worsen ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 20:28:52
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of HYPERTENSION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:21:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: VALSARTAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 22:12:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 22:12:41
Data point term sent to Coder	System	24 Mar 2021 22:11:46
User entered 'VALSARTAN'	(b) (4), (b) (6)	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '320'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '01 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Mar 2021 22:10:59

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 12:18:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 12:18:26
Data point term sent to Coder	System	24 Mar 2021 22:13:48
User entered 'levofloxacin'	(b) (4), (b) (6)	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'port placement'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '500'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '05 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Mar 2021 22:13:09

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE;PRILOCAINE, PRODUCTSYNONYM: EMLA [LIDOCAINE;PRILOCAINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 13:22:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 13:22:17
Data point term sent to Coder	System	24 Mar 2021 22:14:49
User entered 'emla cream'	(b) (4), (b) (6)	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'chemo therapy prophylaxis'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User closed query 'Per DM CLR: Please note, 2.5 % pertains to drug concentration/strength. So please verify if the DOSE reflecting the single dose taken by the subject in # of applications (e.g., Dose=1, If dose unit is Other, specify = application) would be more appropriate recording. If so, update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 20:26:54
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
Query 'Per DM CLR: Please note, 2.5 % pertains to drug concentration/strength. So please verify if the DOSE reflecting the single dose taken by the subject in # of applications (e.g., Dose=1, If dose unit is Other, specify = application) would be more appropriate recording. If so, update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:08:40
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 12:08:20
User opened query 'Per DM CLR: Please note, 2.5 % pertains to drug concentration/strength. So please verify if the DOSE reflecting the single dose taken by the subject in # of applications (e.g., Dose=1, If dose unit is Other, specify = application) would be more appropriate recording. If so, update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:21:33
User entered '2.5'	(b) (4), (b) (6)	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'application' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:08:20
User entered '%'	(b) (4), (b) (6)	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Topical (TOPICAL)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:14:18

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROCHLORPERAZINE MALEATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 09:15:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 09:15:57
Data point term sent to Coder	System	24 Mar 2021 22:16:53
User entered 'prochlorperazine maleate'	(b) (4), (b) (6)	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'non-hodgkin's lymphoma'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '10'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:16:04

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: ALKYLATING AGENTS, ATC: NITROGEN MUSTARD ANALOGUES, PRODUCT: BENDAMUSTINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 12:06:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 12:06:37
Data point term sent to Coder	System	24 Mar 2021 22:18:55
User entered 'bendamustine '	(b) (4), (b) (6)	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'non-hodgkin's lymphoma'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '90'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'every 28 days'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:18:32

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;HYDROCORTISONE;NYST ATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 06:17:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	09 Apr 2021 06:17:39
Data point term sent to Coder	System	24 Mar 2021 22:23:03
User entered 'magic mouthwash (30 ml of nystatin, 60 ml hydrocortisone, diphenhydramine HCL 100mg)'	(b) (4), (b) (6)	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'non-hodgkin's lymphoma'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '30'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:22:34

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: MONOCLONAL ANTIBODIES, PRODUCT: RITUXIMAB - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 04:01:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:01:35
Data point term sent to Coder	System	05 Apr 2021 19:19:44
User entered 'rituximab'	(b) (4), (b) (6)	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'chemotherapy non-hodgkin's lymphoma'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '375'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:19:00

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: ALKYLATING AGENTS, ATC: NITROGEN MUSTARD ANALOGUES, PRODUCT: BENDAMUSTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 19:37:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 19:37:47
Data point term sent to Coder	System	05 Apr 2021 19:36:05
User entered 'BENDAMUSTINE'	(b) (4), (b) (6)	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'non-hodgkin's lymphoma'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '90'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:42:51
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:35:49

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:21:45

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:10
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User closed query 'Per medical records received, it appears subject had a port placed for receiving chemo on 04Jan2021, a retroperitoneal needle biopsy on 18Dec2020. IF confirmed, please consider updating.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:43:38
Query 'Per medical records received, it appears subject had a port placed for receiving chemo on 04Jan2021, a retroperitoneal needle biopsy on 18Dec2020. IF confirmed, please consider updating.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 22:25:32
User opened query 'Per medical records received, it appears subject had a port placed for receiving chemo on 04Jan2021, a retroperitoneal needle biopsy on 18Dec2020. IF confirmed, please consider updating.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 21:56:55
Query 'Per medical records received, it appears subject had a port placed for receiving chemo on 04Jan2021. IF confirmed, please consider updating.' canceled (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 21:26:17
User opened query 'Per medical records received, it appears subject had a port placed for receiving chemo on 04Jan2021. IF confirmed, please consider updating.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 21:20:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:19:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 15:15:45
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 13:19:11

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:21:45

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:50:36
User entered '02 Nov 2020'	(b) (4), (b) (6)	16 Feb 2021 15:16:06

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:21:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:50:36
User entered 'right leg vein ablation'	(b) (4), (b) (6)	16 Feb 2021 15:16:06

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:50:36
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	16 Feb 2021 15:16:06

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:21:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:50:36
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:16:06

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:21:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:27
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:19:54
User entered '06 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 14:19:54
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '18 Dec 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:29:18
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 21:30:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 21:30:18
User entered '15 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 21:30:18
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 21:29:29
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 21:29:29

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:21:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:27
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
User entered 'pet ct' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:19:54
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 14:17:54
User entered 'ct needle biopsy retroperitoneum' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 14:17:54
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'ct angiogram'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:29:29

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:27
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 13:29:40
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 19:30:44
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 20:45:24
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 21:30:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 21:30:18
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 21:30:18
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 21:29:29
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 21:29:29

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:21:45

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:27
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:29:29

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:21:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
User closed query 'Per DM CLR: Please review if this was done for AE#1. If so, please check the Date of this procedure, as it is out of the expected timeframe (18DEC2020 - ongoing). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:31:06
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 14:18:19
User entered '15 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 14:18:19
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
Query 'Per DM CLR: Please review if this was done for AE#1. If so, please check the Date of this procedure, as it is out of the expected timeframe (18DEC2020 - ongoing). Please review and reconcile date of procedure or clarify as necessary. ' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:31:43
User entered '18 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:31:21
User opened query 'Per DM CLR: Please review if this was done for AE#1. If so, please check the Date of this procedure, as it is out of the expected timeframe (18DEC2020 - ongoing). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 20:53:12
User entered '15 Dec 2020'	(b) (4), (b) (6)	24 Mar 2021 21:30:38

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:21:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'CT abdomen/Pelvis'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:30:38

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:30:38

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:21:45

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:30:38

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:21:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User closed query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with AE# 2 (Worsening of Right Leg Varicose Vein, 02 NOV 2020 - 02 NOV 2020). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 13:31:26
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
Query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with AE# 2 (Worsening of Right Leg Varicose Vein, 02 NOV 2020 - 02 NOV 2020). Please review and reconcile date of procedure or clarify as necessary. ' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:32:52
User entered '18 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:32:30
User opened query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with AE# 2 (Worsening of Right Leg Varicose Vein, 02 NOV 2020 - 02 NOV 2020). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 20:55:56
User entered '15 Dec 2020'	(b) (4), (b) (6)	24 Mar 2021 21:30:55

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:21:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'US LOWER EXTREMITIES'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:30:55

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:30:55

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:21:45

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:30:55

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:21:45

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:25:11

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:21:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Port placement'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:25:11

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:25:11

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:21:45

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:25:11

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:21:45

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:25:28

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:21:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'retroperitoneal needle biopsy'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:25:28

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:25:28

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:21:45

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	12 Apr 2021 01:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:25:28

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:21:45

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:19:21

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:21:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
User entered 'chest xray'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:19:21

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:19:21

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:21:45

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:19:21

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:21:45

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:20:21

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:21:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
User entered 'bone marrow aspiration and biopsy'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:20:21

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:21:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:20:21

US3712032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:21:45

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:25:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:10
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:20:21

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'USA-US068-2021-MRNA-1273-P301000014'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'William'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Smith'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered (b) (4)	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:45:06
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:45:06
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered (b) (4)	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:50:14
User entered 'US'	System	18 Feb 2021 19:52:02

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Apr 2021 17:27:15
User entered '5'	System	19 Apr 2021 12:44:00
User entered '4'	System	13 Apr 2021 13:21:08
User entered '3'	System	25 Mar 2021 14:34:24
User entered '2'	System	24 Feb 2021 16:50:42
User entered '1'	System	18 Feb 2021 19:52:02

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'USA-US068-2021-MRNA-1273-P301000014'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'William'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Smith'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	25 Mar 2021 14:34:24
User entered (b) (4) '	System	25 Mar 2021 14:34:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:34:01
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:45:06
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:45:06
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered (b) (4)	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:50:14
User entered 'US'	System	18 Feb 2021 19:52:02

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Apr 2021 17:27:15
User entered '5'	System	19 Apr 2021 12:44:00
User entered '4'	System	13 Apr 2021 13:21:08
User entered '3'	System	25 Mar 2021 14:34:24
User entered '2'	System	24 Feb 2021 16:50:42
User entered '1'	System	18 Feb 2021 19:52:02

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:21:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered '18/Feb/2021 14:52'	(b) (4) System	18 Feb 2021 19:52:02

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:21:45

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 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:50:14
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 19:52:02

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'USA-US068-2021-MRNA-1273-P301000014'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'William'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Smith'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	25 Mar 2021 14:34:24
User entered (b) (4) '	System	25 Mar 2021 14:34:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:34:01
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:45:06
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:45:06
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered (b) (4) '	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:50:14
User entered 'US'	System	18 Feb 2021 19:52:02

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Apr 2021 17:27:15
User entered '5'	System	19 Apr 2021 12:44:00
User entered '4'	System	13 Apr 2021 13:21:08
User entered '3'	System	25 Mar 2021 14:34:24
User entered '2'	System	24 Feb 2021 16:50:42
User entered '1'	System	18 Feb 2021 19:52:02

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:21:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered '24/Feb/2021 16:50'	(b) (4) System	24 Feb 2021 16:50:42

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:21:45

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 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 16:50:42

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'USA-US068-2021-MRNA-1273-P301000014'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'William'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Smith'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	25 Mar 2021 14:34:24
User entered (b) (4)	System	25 Mar 2021 14:34:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:34:01
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:45:06
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:45:06
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered (b) (4) '	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:50:14
User entered 'US'	System	18 Feb 2021 19:52:02

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Apr 2021 17:27:15
User entered '5'	System	19 Apr 2021 12:44:00
User entered '4'	System	13 Apr 2021 13:21:08
User entered '3'	System	25 Mar 2021 14:34:24
User entered '2'	System	24 Feb 2021 16:50:42
User entered '1'	System	18 Feb 2021 19:52:02

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:21:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered '25/Mar/2021 14:34'	(b) (4) System	25 Mar 2021 14:34:24

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:21:45

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 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:34:24

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'USA-US068-2021-MRNA-1273-P301000014'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'William'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Smith'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered (b) (4)	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:45:06
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:45:06
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered (b) (4) '	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:50:14
User entered 'US'	System	18 Feb 2021 19:52:02

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Apr 2021 17:27:15
User entered '5'	System	19 Apr 2021 12:44:00
User entered '4'	System	13 Apr 2021 13:21:08
User entered '3'	System	25 Mar 2021 14:34:24
User entered '2'	System	24 Feb 2021 16:50:42
User entered '1'	System	18 Feb 2021 19:52:02

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:21:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
User entered '13/Apr/2021 06:21'	(b) (4) System	13 Apr 2021 13:21:08

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:21:45

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 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:21:08

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'USA-US068-2021-MRNA-1273-P301000014'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'William'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Smith'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
Un-reviewed for Safety.	System	25 Mar 2021 14:34:24
User entered (b) (4)	System	25 Mar 2021 14:34:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 14:34:01
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:45:06
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:45:06
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered (b) (4) '	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:50:14
User entered 'US'	System	18 Feb 2021 19:52:02

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Apr 2021 17:27:15
User entered '5'	System	19 Apr 2021 12:44:00
User entered '4'	System	13 Apr 2021 13:21:08
User entered '3'	System	25 Mar 2021 14:34:24
User entered '2'	System	24 Feb 2021 16:50:42
User entered '1'	System	18 Feb 2021 19:52:02

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:21:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:39:25
User entered '19/Apr/2021 08:43'	System	19 Apr 2021 12:44:00

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:21:45

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 21:38:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 12:44:00

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'USA-US068-2021-MRNA-1273-P301000014'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'No (N)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Yes (Y)'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'William'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered 'Smith'	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:45:06

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:43:44
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Un-reviewed for Safety.	(b) (4)	
User entered (b) (4)	System	25 Mar 2021 14:34:24
Reviewed for Safety.	System	25 Mar 2021 14:34:24
	(b) (4), (b) (6)	25 Mar 2021 14:34:01
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:45:06
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:45:06
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:51:53
User entered (b) (4) '	System	18 Feb 2021 19:51:25

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:50:14
User entered 'US'	System	18 Feb 2021 19:52:02

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Apr 2021 17:27:15
User entered '5'	System	19 Apr 2021 12:44:00
User entered '4'	System	13 Apr 2021 13:21:08
User entered '3'	System	25 Mar 2021 14:34:24
User entered '2'	System	24 Feb 2021 16:50:42
User entered '1'	System	18 Feb 2021 19:52:02

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:21:45

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:28
User entered '23/Apr/2021 13:27'	(b) (4) System	23 Apr 2021 17:27:15

US3712032

Folder: SAE USA-US068-2021-MRNA-1273-P301000014

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:21:45

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 21:38:28
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:27:15