

US3862007 (Prod: Baylor College of Medicine)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:06:10

All time stamps listed in this document are displayed in GMT

US3862007

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 14:03:48

Generated On: 10 Jun 2021 10:06:10

[Participant ID](#)

US3862007

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

US3862007

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 13 AUG 2020

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

Folder OID SCRN

US3862007

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:30:13

Generated On: 10 Jun 2021 10:06:10

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	65
Age Units	YEARS
Age (Derived)	65
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

US3862007

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 00:30:13

Generated On: 10 Jun 2021 10:06:10

Date of Informed Consent (*dd MMM yyyy*) 13 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3862007

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 00:30:13

Generated On: 10 Jun 2021 10:06:10

Did the participant meet all eligibility criteria?

Yes

No

US3862007

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Were any significant conditions reported?

Yes

No

US3862007

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3862007

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	PAPILLARY THYROID CARCINOMA
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

US3862007

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	
Stop Year (derived)	

US3862007

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3862007

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3862007

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	ANTERIOR TIBIAL VEIN THROMBOSIS
Start date (dd MMM yyyy)	20 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

US3862007

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	GENITAL HERPES
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Start Year (derived)	1987
Stop Month and Year (derived)	
Stop Year (derived)	

US3862007

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	UN MAR 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)	MAR 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

US3862007

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	OSTEOARTHRITIS
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)	

US3862007

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	KNEE REPLACEMENT (LEFT)
Start date (dd MMM yyyy)	16 DEC 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)	16 DEC 2019
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	DEC 2019
Stop Year (derived)	2019

US3862007

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	TOTAL HIP REPLACEMENT (RIGHT)
Start date (dd MMM yyyy)	UN JAN 2013
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 JAN 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3862007

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	TOTAL ABDOMINAL HYSTERECTOMY
Start date (dd MMM yyyy)	UN SEP 2006
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 2006
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2006
Start Year (derived)	2006
Stop Month and Year (derived)	SEP 2006
Stop Year (derived)	2006

US3862007

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	THYROIDECTOMY
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

US3862007

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	BILATERAL SALPINGO-OOPHORECTOMY
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

US3862007

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	IRON DEFICIENCY ANEMIA
Start date (dd MMM yyyy)	UN SEP 2017
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 DEC 2017
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2017
Start Year (derived)	2017
Stop Month and Year (derived)	DEC 2017
Stop Year (derived)	2017

US3862007

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	EXTERNAL THROMOBOSED HEMORRHOIDS
Start date (dd MMM yyyy)	UN JUN 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 JUL 2009
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JUL 2009
Stop Year (derived)	2009

US3862007

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	GESTATIONAL DIABETES
Start date (dd MMM yyyy)	UN JUN 1983
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 DEC 1983
Stop date completely unknown	False
Start Month and Year (derived)	JUN 1983
Start Year (derived)	1983
Stop Month and Year (derived)	DEC 1983
Stop Year (derived)	1983

US3862007

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	CESARIAN SECTION
Start date (dd MMM yyyy)	UN DEC 1983
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 DEC 1983
Stop date completely unknown	False
Start Month and Year (derived)	DEC 1983
Start Year (derived)	1983
Stop Month and Year (derived)	DEC 1983
Stop Year (derived)	1983

US3862007

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	CESARIAN SECTION
Start date (dd MMM yyyy)	UN DEC 1995
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 DEC 1995
Stop date completely unknown	False
Start Month and Year (derived)	DEC 1995
Start Year (derived)	1995
Stop Month and Year (derived)	DEC 1995
Stop Year (derived)	1995

US3862007

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	OBESITY
Start date (dd MMM yyyy)	UN JAN 1984
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 1984
Start Year (derived)	1984
Stop Month and Year (derived)	
Stop Year (derived)	

US3862007

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 23 Apr 2021 13:58:20

Generated On: 10 Jun 2021 10:06:10

Condition	OSTEOPENIA
Start date (dd MMM yyyy)	01 SEP 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3862007

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 13 AUG 2020

Time of assessment (00:00-23:59) 10:30 (24 HR)

Vital Signs Date and Time (derived) 13 AUG 2020 10:30

Height (xxx.x) 64.0 in

Weight (xxx.x) 224.6 lb

BMI (xxx.x) 38.63311 kg/m²

BMI units KG/M2

Temperature (xxx.x) ND - Not Done

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) ND - Not Done

Pulse units BPM

Respiratory Rate (xxx) ND - Not Done

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) ND - Not Done

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) ND - Not Done

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3862007

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

13 AUG 2020

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

US3862007

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 00:30:13

Generated On: 10 Jun 2021 10:06:10

Date of assessment (*dd MMM yyyy*) 13 AUG 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 SEP 2006

Date of surgery unknown False

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

Date of last menstruation unknown False

US3862007

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

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

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3862007

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 13 AUG 2020

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

Folder OID VISIT1

US3862007

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 185289

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

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Height	ND - Not Done
Weight	ND - Not Done

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:30 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 10:30
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	65 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	57 mmHg
Diastolic Blood Pressure units	MMHG

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Height	ND - Not Done
Weight	ND - Not Done
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 (<i>dd MMM yyyy</i>)	13 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:00 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 13:00
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input type="checkbox"/> Axillary <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3862007

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

13 AUG 2020

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

US3862007

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

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) 13 AUG 2020

What was the treatment time? (00:00-23:59) 12:29 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 12:29

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

US3862007

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 13 AUG 2020

Collection time (*00:00-23:59*) 11:23 (24 HR)

Collection date and time (derived) 13 AUG 2020 11:23

US3862007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Collection date (<i>dd MMM yyyy</i>)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:02	13 AUG 2020 11:02
Nasopharyngeal Swab 2	No		

US3862007

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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 97.8 °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 13 AUG 2020 13:05

PC Open Date & Time 13 AUG 2020 12:49

PC Close Date & Time 13 AUG 2020 15:19

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	13 AUG 2020 21:01
PC Open Date & Time	13 AUG 2020 16:14
PC Close Date & Time	14 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:10

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	96.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	14 AUG 2020 22:20
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:10

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	16 AUG 2020 00:22
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:10

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	16 AUG 2020 21:37
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:10

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	17 AUG 2020 23:01
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	18 AUG 2020 21:21
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:10

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 <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 type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 AUG 2020 11:47
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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	13 AUG 2020 13:06
PC Open Date & Time	13 AUG 2020 12:49
PC Close Date & Time	13 AUG 2020 15:19

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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	13 AUG 2020 21:04
PC Open Date & Time	13 AUG 2020 16:14
PC Close Date & Time	14 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 2

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	14 AUG 2020 22:25
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	16 AUG 2020 00:23
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

16 AUG 2020 21:37

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

17 AUG 2020 23:02

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 6

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	18 AUG 2020 21:21
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 7

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

20 AUG 2020 11:47

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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

No

Yes

PC Time stamp	13 AUG 2020 13:06
PC Open Date & Time	13 AUG 2020 12:49
PC Close Date & Time	13 AUG 2020 15:19

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

No
Yes

PC Time stamp	13 AUG 2020 21:04
PC Open Date & Time	13 AUG 2020 16:14
PC Close Date & Time	14 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

	Yes <input type="checkbox"/>
PC Time stamp	14 AUG 2020 22:25
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

	Yes <input type="checkbox"/>
PC Time stamp	16 AUG 2020 00:23
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

Yes

PC Time stamp	16 AUG 2020 21:37
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

	Yes <input type="checkbox"/>
PC Time stamp	17 AUG 2020 23:03
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

	Yes <input type="checkbox"/>
PC Time stamp	18 AUG 2020 21:22
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

	Yes <input type="checkbox"/>
PC Time stamp	20 AUG 2020 11:47
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3862007

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:30:13

Generated On: 10 Jun 2021 10:06:10

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 20 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3862007

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:30:13

Generated On: 10 Jun 2021 10:06:10

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3862007

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:30:13

Generated On: 10 Jun 2021 10:06:10

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 27 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3862007

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:30:13

Generated On: 10 Jun 2021 10:06:10

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3862007

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:30:13

Generated On: 10 Jun 2021 10:06:10

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 3 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3862007

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:30:13

Generated On: 10 Jun 2021 10:06:10

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3862007

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 10 SEP 2020

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

Folder OID VISIT2

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

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 (<i>dd MMM yyyy</i>)	10 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:51 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 15:51
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	17:26 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 17:26
Temperature (<i>xxx.x</i>)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	65 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3862007

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

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.

US3862007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

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) 16:48 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 16:48

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

US3862007

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 10 SEP 2020

Collection time (*00:00-23:59*) 16:08 (24 HR)

Collection date and time (derived) 10 SEP 2020 16:08

US3862007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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 98.8 °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 SEP 2020 17:29

PC Open Date & Time 10 SEP 2020 17:08

PC Close Date & Time 10 SEP 2020 19:38

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 10 SEP 2020 20:33

PC Close Date & Time 11 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:10

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** 100.8 °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 11 SEP 2020 17:18

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:10

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 SEP 2020 18:33
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:10

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	13 SEP 2020 22:48
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:10

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	14 SEP 2020 19:21
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

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 _____
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 _____
To **PREVENT** pain or fever from occurring _____
PC Time Stamp _____
PC Open Date & Time 15 SEP 2020 12:00
PC Close Date & Time 16 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:10

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

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

Yes

No

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

PC Time Stamp

17 SEP 2020 11:13

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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 17:30
PC Open Date & Time	10 SEP 2020 17:08
PC Close Date & Time	10 SEP 2020 19:38

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

10 SEP 2020 20:33

PC Close Date & Time

11 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

2

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	11 SEP 2020 17:21
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

50

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

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

- Yes
- No

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

2

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

12 SEP 2020 18:35

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 4

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

10

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

13 SEP 2020 22:49

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

2

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	14 SEP 2020 19:22
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 6

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

17 SEP 2020 11:19

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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

No

Yes

PC Time stamp	10 SEP 2020 17:30
PC Open Date & Time	10 SEP 2020 17:08
PC Close Date & Time	10 SEP 2020 19:38

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

No

Yes

PC Time stamp

PC Open Date & Time

10 SEP 2020 20:33

PC Close Date & Time

11 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

	Yes <input type="checkbox"/>
PC Time stamp	11 SEP 2020 17:22
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

	Yes <input type="checkbox"/>
PC Time stamp	12 SEP 2020 18:36
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

	Yes <input type="checkbox"/>
PC Time stamp	13 SEP 2020 22:50
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

	Yes <input type="checkbox"/>
PC Time stamp	14 SEP 2020 19:22
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

Yes

PC Time stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

	Yes <input type="checkbox"/>
PC Time stamp	17 SEP 2020 11:19
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3862007

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:30:13

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:30:13

Generated On: 10 Jun 2021 10:06:10

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3862007

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:30:13

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:30:13

Generated On: 10 Jun 2021 10:06:10

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3862007

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:30:13

Generated On: 10 Jun 2021 10:06:10

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 1 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3862007

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:30:13

Generated On: 10 Jun 2021 10:06:10

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3862007

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 6 OCT 2020

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

Folder OID VISIT3

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	6 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:55 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 15:55
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862007

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

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.

US3862007

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	6 OCT 2020
Collection time (<i>00:00-23:59</i>)	15:34 (24 HR)
Collection date and time (derived)	6 OCT 2020 15:34

US3862007

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:30:14

Generated On: 10 Jun 2021 10:06:10

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	True
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	10 NOV 2020 06:55:40
Patient Cloud Open Date & Time	10 NOV 2020 00:01

PRODUCTION RELEASE (v12.003
EAB) (1725)

140 of 2752

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

14 NOV 2020 23:59

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	_____
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 <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"/>

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 103

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 110

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

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 117

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

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 05 DEC 2020 00:01

[Patient Cloud Close Date & Time](#) 09 DEC 2020 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 01:14:55
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 08:20:00
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 DEC 2020 11:42:18
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 11:21:10
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 152

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

No

Yes

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

No

Yes

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

Date and time of submission 09 JAN 2021 00:01:53

Patient Cloud Open Date & Time 09 JAN 2021 00:01

Patient Cloud Close Date & Time 13 JAN 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 00:05:59
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 166

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

No

Yes

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

No

Yes

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

Date and time of submission 23 JAN 2021 11:20:44

Patient Cloud Open Date & Time 23 JAN 2021 00:01

Patient Cloud Close Date & Time 27 JAN 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 173

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

No

Yes

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

No

Yes

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

Date and time of submission 30 JAN 2021 11:21:56

Patient Cloud Open Date & Time 30 JAN 2021 00:01

Patient Cloud Close Date & Time 03 FEB 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 16:42:51
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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 FEB 2021 10:58:01

Patient Cloud Open Date & Time 13 FEB 2021 00:01

Patient Cloud Close Date & Time 17 FEB 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 FEB 2021 10:31:11
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 FEB 2021 10:32:05
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	06 MAR 2021 10:54:40
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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 <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 MAR 2021 07:30:59
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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 20 MAR 2021 00:17:09

Patient Cloud Open Date & Time 20 MAR 2021 00:01

Patient Cloud Close Date & Time 24 MAR 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 MAR 2021 10:31:59
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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 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 APR 2021 00:03:30
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 243

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

No

Yes

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

No

Yes

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

Date and time of submission 10 APR 2021 10:31:45

Patient Cloud Open Date & Time 10 APR 2021 00:01

Patient Cloud Close Date & Time 14 APR 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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 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	17 APR 2021 00:55:10
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 APR 2021 10:36:57
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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 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	01 MAY 2021 10:31:54
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 320

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 327

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 334

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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
Yes

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 348

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 383

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission	
Patient Cloud Open Date & Time	04 SEP 2021 00:01
Patient Cloud Close Date & Time	08 SEP 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 404

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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
Yes

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 06 OCT 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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
Yes

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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 Yes

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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	13 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 467

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission	
Patient Cloud Open Date & Time	20 NOV 2021 00:01
Patient Cloud Close Date & Time	24 NOV 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 481

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 488

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 544

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission	
Patient Cloud Open Date & Time	12 FEB 2022 00:01
Patient Cloud Close Date & Time	16 FEB 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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
Yes

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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
Yes

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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 Yes

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 635

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 691

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 719

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 726

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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
Yes

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 754

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission	
Patient Cloud Open Date & Time	03 SEP 2022 00:01
Patient Cloud Close Date & Time	07 SEP 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

DAY 768

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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°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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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	08 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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 Yes

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

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:06:10

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 10:32:23

US3862007

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:24:42

Generated On: 10 Jun 2021 10:06:10

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 5 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3862007

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:24:42

Generated On: 10 Jun 2021 10:06:10

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3862007

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:03:49

Generated On: 10 Jun 2021 10:06:10

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3862007

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:03:49

Generated On: 10 Jun 2021 10:06:10

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3862007

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:03:50

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:03:49

Generated On: 10 Jun 2021 10:06:10

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3862007

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:03:50

Generated On: 10 Jun 2021 10:06:10

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 09 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3862007

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:03:50

Generated On: 10 Jun 2021 10:06:10

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3862007

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:03:50

Generated On: 10 Jun 2021 10:06:10

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 22 MAR 2021

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

Folder OID VISIT4

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 14:03:50

Generated On: 10 Jun 2021 10:06:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	22 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	15:14 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 15:14
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862007

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:03:50

Generated On: 10 Jun 2021 10:06:10

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3862007

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:03:50

Generated On: 10 Jun 2021 10:06:10

Was the sample collected? Yes No

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

Collection time (*00:00-23:59*) 15:34 (24 HR)

Collection date and time (derived) 22 MAR 2021 15:34

US3862007

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:03:50

Generated On: 10 Jun 2021 10:06:10

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3862007

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 18:31:36

Generated On: 10 Jun 2021 10:06:10

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3862007

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 18:31:36

Generated On: 10 Jun 2021 10:06:10

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3862007

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

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 _____

US3862007

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3862007

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:06:10

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"/>

US3862007

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:06:10

Generate Next COVID-19 Assessment

Yes

No

US3862007

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:03:49

Generated On: 10 Jun 2021 10:06:10

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 05 JAN 2021

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

Folder OID UNBLND_DECIDE

US3862007

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 14:03:49

Generated On: 10 Jun 2021 10:06:10

Date of updated informed consent (*dd MMM yyyy*) 05 JAN 2021

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

Was the participant unblinded? Yes
No

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

Date of unblinding (*dd MMM yyyy*) 05 JAN 2021

Participant randomization assignment mRNA-1273
Placebo

Actual Dose 1 mRNA-1273
Placebo
Not Administered

Actual Dose 2 mRNA-1273
Placebo
Not Administered

Will participant receive mRNA-1273? Yes
No

Placebo Only Flag _____

Continuing with mRNA-1273 _____

US3862007

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:03:49

Generated On: 10 Jun 2021 10:06:10

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 05 JAN 2021

Collection time (*00:00-23:59*) 11:38 (24 HR)

Collection date and time (derived) 05 JAN 2021 11:38

US3862007

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 14:03:49

Generated On: 10 Jun 2021 10:06:10

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 05 JAN 2021

Collection time (*00:00 - 23:59*) 11:32

Collection Date and Time (derived) 05 JAN 2021 11:32

US3862007

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Mar 2021 15:10:48

Generated On: 10 Jun 2021 10:06:10

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

AEID

Adverse event

INJECTION SITE BRUISE

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) 10 SEP 2020

Start time (00:00-23:59) 16:48 (24 HR)

AE start date and time (derived) 10 SEP 2020 16:48

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 14 SEP 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

Number of Days in ICU

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 2752

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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 type="radio"/> Related <input checked="" 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 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

AEID	
Adverse event	NECK PAIN
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	8 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 NOV 2020
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"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

350 of 2752

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

AEID	
Adverse event	VIRAL UPPER RESPIRATORY SYMPTOMS
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Start date (dd MMM yyyy)	5 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	7 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
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="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

CLARIFICATION REGARDING
AE:
SUBJECT HAD MILD
INTERMITTENT NASAL
CONGESTION, RHINORRHEA
AND SORE THROAT FROM 05
-07 DEC 2020. EXPOSED TO
RELATIVE WHO HAD
RHINOVIRUS. TOOK ALKA
SELTZER COLD AND FLU
MEDICATIONS. SUBJECT DID
NOT CALL SITE OR REPORT
SYMPTOMS IN EDIARY.
ILLNESS VISIT NOT DONE.
PROTOCOL DEVIATION
CREATED

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

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

AEID USA-US121-2021-MRNA-1273-P30
1000005

Adverse event ACUTE KIDNEY INJURY

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) 11 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 14 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 11 MAR 2021

Hospital Discharge Date (dd MMM yyyy) 14 MAR 2021

Admitted to ICU? Yes
No
Unknown

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

MRNA-1273-P301

SUBJECT: US3862007

67 YEARS OLD CAUCASIAN
FEMALE
MEDICAL HISTORY: TYPE 2 DM,
HYPERLIPIDEMIA,
HYPOTHYROIDISM, SEASONAL
ALLERGIES, OSTEOARTHRITIS
MEDICATION: METFORMIN,
SIMVASTATIN, LEVOXYL,
IBUPROFEN, CELEBREX

AMENDMENT 6 PROTOCOL
UNBLINDED: 05 JAN 2021
RANDOMIZED TREATMENT
ARM: MRNA 1273
FIRST DOSE: 13 AUG 2020
SECOND DOSE: 10 SEP 2020

11 MAR 2021: SUBJECT CALLED
SITE TO RESCHEDULE HER
VISIT 4 SINCE SHE WAS NOT
FEELING WELL. REPORTED
WAKING UP WITH A STRANGE
SENSATION IN HER HEAD,
FEELING OF THICK SENSATION
IN HER TONGUE WITH
DIFFICULTY PRONOUNCING
SOME WORDS. NOTED MILD
SLURRING AND DRAGGING OF
WORDS DURING OUR
CONVERSATION. SUBJECT WAS
INSTRUCTED RIGHT AWAY TO
SEEK IMMEDIATE

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

MEDICAL HELP (CALL 911).
12 MARCH 2021: FOLLOW-UP
PHONE CALL. SUBJECT
REPORTED THAT SHE WAS
ADMITTED IN THE HOSPITAL
SINCE YESTERDAY (11 MAR
2021). CT SCAN OF BRAIN AND
MRI OF BRAIN: NO
SIGNIFICANT FINDINGS.
BLOOD WORK UP REVEALED:
CREATININE LEVEL 3.4 MG/DL,
GFR LEVEL 15 ML/MIN.
CURRENTLY RECEIVING
INTRAVENOUS HYDRATION.
SUBJECT WILL BE FOLLOWED
UP CLOSELY. MEDICAL
RECORDS WILL BE REQUESTED
ONCE DISCHARGED FROM THE
HOSPITAL.
12 APR 2021:
SUBJECT PRESENTED WITH
ACUTE ONSET OF TRANSIENT
SLURRED SPEECH AND RIGHT
LEG WEAKNESS. CT BRAIN-
NEGATIVE, MRI
BRAIN-NEGATIVE,
NEUROLOGIST DETERMINED
NEUROLOGICAL ISSUES
RELATED TO ACUTE KIDNEY
INJURY. MRA HEAD AND NECK-
POSSIBLE ANEURYSM 2-3MM
LEFT UPPER INTERNAL
CAROTID ARTERY.
CARDIOLOGIST
RECOMMENDATION-NO

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

INTERVENTION, FOLLOW-UP
ANNUAL IMAGING.ACUTE
KIDNEY INJURY DETERMINED
RELATED TO NSAIDS USE.
CELEBREX, IBUPROFEN AND
VITAMIN D DISCONTINUED.
TREATMENT- IV HYDRATION
OF NORMAL SALINE
SOLUTION. BASELINE
CREATININE 3.97 IMPROVED TO
1.8 MG/DL.

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

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

AEID

Adverse event

URINARY TRACT INFECTION

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)

11 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

25 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

PRODUCTION RELEASE (v12.003

360 of 2752

EAB) (1725)

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

AEID

Adverse event

SUSPECTED INTERNAL
CAROTID ARTERY ANEURYSM

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)

11 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

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

362 of 2752

EAB) (1725)

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
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)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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

Yes

No

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

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication METFORMIN

Prophylaxis Yes
No

Indication TYPE 2 DIABETES

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
EAB) (1725)

365 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication COLACE

Prophylaxis Yes
No

Indication CONSTIPATION

Dose per administration 100

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

367 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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 2017

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication VITAMIN C

Prophylaxis Yes
No

Indication PROPHYLAXIS FOR
NUTRITIONAL DEFICIENCY

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

369 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	UN UNK 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"/>

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication IRON SULFATE

Prophylaxis Yes
No

Indication PROPHYLAXIS FOR
NUTRITIONAL DEFICIENCY

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)

371 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2017

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication ZYRTEC

Prophylaxis Yes
No

Indication SEASONAL ALLERGIES

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

373 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication SUPERFICIAL THROMBOSIS

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)

375 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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 JUL 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication SIMVASTATIN

Prophylaxis Yes
No

Indication HYPERLIPIDEMIA

Dose per administration 20

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

377 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication LEVOXYL

Prophylaxis Yes
No

Indication HYPOTHYROIDISM

Dose per administration 112

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

379 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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 1985

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication VALTRESX

Prophylaxis Yes
No

Indication GENITAL HERPES

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

381 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication VITAMIN D3

Prophylaxis Yes
No

Indication GENERAL HEALTH

Dose per administration 5000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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 MAR 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 12 MAR 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication ZINC

Prophylaxis Yes
No

Indication GENERAL HEALTH

Dose per administration 25

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

385 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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 MAR 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication MELATONIN

Prophylaxis Yes
No

Indication SLEEP AIDE

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

387 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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 2017

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication OSTEOARTHRITIS

Dose per administration 600

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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 1980

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 12 MAR 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication MULTIVITAMIN

Prophylaxis Yes
No

Indication GENERAL HEALTH

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
EAB) (1725)

391 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication VOLTAREN GEL

Prophylaxis Yes
No

Indication OSTEOARTHRITIS

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

393 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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*) 28 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 28 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication CELEBREX

Prophylaxis Yes
No

Indication OSTEOARTHRITIS

Dose per administration 200

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

395 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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*) 28 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 5 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication CELEBREX

Prophylaxis Yes
No

Indication OSTEOARTHRITIS

Dose per administration 200

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

397 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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*) 6 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 12 MAR 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication FLU VACCINE, FLUZONE

Prophylaxis Yes
No

Indication PREVENTION OF INFLUENZA

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)

399 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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*) 2 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 2 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication BIOFREEZE ROLL-ON
MENTHOL 3.5%

Prophylaxis Yes
No

Indication NECK PAIN

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)

401 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

	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) 8 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 10 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication NECK PAIN

Dose per administration 600

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

403 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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*) 8 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 8 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication NECK PAIN

Dose per administration 800

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)

405 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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*) 9 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 9 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication ALKA-SELTZER COLD AND FLU
(ACETAMINOPHEN 250
MG,CHLORPHENIRAMINE
MALEATE 2MG,
DEXTROMETHORPHAN
HYDROBROMIDE 10 MG)

Prophylaxis Yes
No

Indication VIRAL UPPER RESPIRATORY
SYMPTOMS

Dose per administration 500/4/20

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

407 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

	Topical	<input type="checkbox"/>
	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) 5 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 7 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication NEUROLOGIC ISSUE DUE TO ACUTE KIDNEY INJURY

Dose per administration 325

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

409 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

	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) 11 MAR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 11 MAR 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication NORMAL SALINE SOLUTION

Prophylaxis Yes
No

Indication ACUTE KIDNEY INJURY

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

411 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input checked="" type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 11 MAR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 11 MAR 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication LORAZEPAM

Prophylaxis Yes
No

Indication MRI

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
EAB) (1725)

413 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input checked="" type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 11 MAR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 11 MAR 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Name of Medication NITROFURANTOIN

Prophylaxis Yes
No

Indication URINARY TRACT INFECTION

Dose per administration 100

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

415 of 2752

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

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 (<i>dd MMM yyyy</i>)	16 MAR 2021
-----------------------------------	-------------

Start date completely unknown	False
-------------------------------	-------

Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

If not Ongoing, End date (<i>dd MMM yyyy</i>)	25 MAR 2021
---	-------------

Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

Separate Dosage Number (derived)	2
----------------------------------	---

Interval Dosage Unit Number (derived)	1
---------------------------------------	---

Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 14:03:49

Generated On: 10 Jun 2021 10:06:10

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 MAR 2021	CT SCAN OF BRAIN	Adverse Event	
11 MAR 2021	MRI OF BRAIN	Adverse Event	
11 MAR 2021	CHEST XRAY	Adverse Event	
11 MAR 2021	MRA HEAD AND NECK	Adverse Event	
11 MAR 2021	EKG	Adverse Event	
12 MAR 2021	RENAL ULTRASOUND	Adverse Event	

US3862007

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:06:10

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

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

SAEID	USA-US121-2021-MRNA-1273-P30 1000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

SAEID USA-US121-2021-MRNA-1273-P30
1000005

Serious Yes
No

Death Yes
No

Life threatening Yes
No

Requires inpatient or prolongation of existing Hospitalization Yes
No

Persistent or significant disability or incapacity Yes
No

Congenital anomaly or birth defect Yes
No

Other medically important event Yes
No

Investigator's First Name THEA MARIE

Investigator's Last Name CORDERO

Site Address: Street ONE BAYLOR PLAZA, MS 280,
ROOM 221D

Site Address: City HOUSTON

Site Address: State TX

Site Address: Postal Code 77030

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 3

Date of submission (Pre-filled from custom function) 15/MAR/2021 10:09

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

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

SAEID	USA-US121-2021-MRNA-1273-P30 1000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	23/MAR/2021 07:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 15 Apr 2021 21:40:07

Generated On: 10 Jun 2021 10:06:10

SAEID USA-US121-2021-MRNA-1273-P30
1000005

Serious Yes
No

Death Yes
No

Life threatening Yes
No

Requires inpatient or prolongation of existing Hospitalization Yes
No

Persistent or significant disability or incapacity Yes
No

Congenital anomaly or birth defect Yes
No

Other medically important event Yes
No

Investigator's First Name THEA MARIE

Investigator's Last Name CORDERO

Site Address: Street ONE BAYLOR PLAZA, MS 280,
ROOM 221D

Site Address: City HOUSTON

Site Address: State TX

Site Address: Postal Code 77030

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 3

Date of submission (Pre-filled from custom function) 13/APR/2021 11:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. True

Audit

US3862007 (Prod: Baylor College of Medicine)

US3862007

Form: Participant Creation

Generated On: 10 Jun 2021 10:06:10

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'US3862007'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:19:14

US3862007

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 16:20:01

US3862007

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:19:15

US3862007

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Clinic (Clinic)'	Coni Cheesman (b) (4)	13 Aug 2020 16:20:01

US3862007

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'SCRN'	System	13 Aug 2020 16:20:01

US3862007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:10

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:19:16

US3862007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:10

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '65'	Coni Cheesman (b) (4)	13 Aug 2020 16:20:21

US3862007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:10

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'YEARS'	System	13 Aug 2020 16:20:21

US3862007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:10

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '65'	System	13 Aug 2020 16:33:05

US3862007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:10

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Female (F)'	Coni Cheesman (b) (4)	13 Aug 2020 16:20:21

US3862007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:10

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Coni Cheesman (b) (4)	13 Aug 2020 16:20:21

US3862007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:10

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '1'	Coni Cheesman (b) (4)	13 Aug 2020 16:20:21

US3862007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:10

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 16:20:21

US3862007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:10

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 16:20:21

US3862007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:10

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 16:20:21

US3862007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:10

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 16:20:21

US3862007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 16:20:21

US3862007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:10

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 16:20:21

US3862007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:10

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 16:20:21

US3862007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:10

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 16:20:21

US3862007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:10

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '13 Aug 2020'	Coni Cheesman (b) (4)	13 Aug 2020 16:33:05

US3862007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Aug 2020'	System	13 Aug 2020 16:33:05

US3862007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2020'	System	13 Aug 2020 16:33:05

US3862007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:10

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Amendment 2 (2)'	Coni Cheesman (b) (4)	13 Aug 2020 16:33:05

US3862007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 16:33:05

US3862007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:10

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 16:33:05

US3862007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:10

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 16:33:05

US3862007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:10

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:33:05

US3862007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:10

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:19:15

US3862007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:10

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '1'	System	13 Aug 2020 16:33:05

US3862007

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 16:19:42

US3862007

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:06:10

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 16:40:07

US3862007

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 18:41:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 18:41:27
Data point term sent to Coder	System	13 Aug 2020 18:40:04
User entered 'diabetes mellitus type 2'	Carrie Kibler (b) (4)	13 Aug 2020 18:39:33

US3862007

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'un UNK 2015'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:39:33

US3862007

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:39:33

US3862007

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:39:33

US3862007

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:39:33

US3862007

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:39:33

US3862007

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jan 2015'	System	13 Aug 2020 18:39:33

US3862007

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2015'	System	13 Aug 2020 18:39:33

US3862007

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	13 Aug 2020 18:39:33

US3862007

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	13 Aug 2020 18:39:33

US3862007

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
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)	13 Aug 2020 18:42:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 18:42:28
Data point term sent to Coder	System	13 Aug 2020 18:41:07
User entered 'hyperlipidemia'	Carrie Kibler (b) (4)	13 Aug 2020 18:40:36

US3862007

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'un UNK 2014'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:40:36

US3862007

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:40:36

US3862007

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:40:36

US3862007

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:40:36

US3862007

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:40:36

US3862007

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jan 2014'	System	13 Aug 2020 18:40:36

US3862007

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2014'	System	13 Aug 2020 18:40:36

US3862007

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	13 Aug 2020 18:40:36

US3862007

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	13 Aug 2020 18:40:36

US3862007

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Endocrine neoplasms malignant and unspecified, HLT: Thyroid neoplasms malignant, PT: Papillary thyroid cancer, LLT: Thyroid papillary carcinoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 09:34:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 09:34:11
Data point term sent to Coder	System	13 Aug 2020 18:41:08
User entered 'papillary thyroid carcinoma'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:40:53

US3862007

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'un UNK 1985'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:40:53

US3862007

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:40:53

US3862007

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Aug 2020 18:46:10
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	13 Aug 2020 18:40:53

US3862007

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'un UNK 1985' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Aug 2020 18:46:10
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	13 Aug 2020 18:40:53
	(b) (4)	

US3862007

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:40:53

US3862007

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jan 1985'	System	13 Aug 2020 18:40:53

US3862007

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '1985'	System	13 Aug 2020 18:40:53

US3862007

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jan 1985'	System	13 Aug 2020 18:46:10
User entered empty.	System	13 Aug 2020 18:40:53

US3862007

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '1985'	System	13 Aug 2020 18:46:10
User entered empty.	System	13 Aug 2020 18:40:53

US3862007

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User coded data point as SOC: Nervous system disorders, HLGT: Sleep disturbances (incl subtypes), HLT: Narcolepsy and hypersomnia, PT: Narcolepsy, LLT: Narcolepsy - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:45:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:45:23
Data point term sent to Coder	System	13 Aug 2020 18:44:13
User entered 'Narcolepsy'	Carrie Kibler (b) (4)	13 Aug 2020 18:43:33
DataPoint activated with code reason code Data required.	(b) (4)	13 Aug 2020 18:43:03
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	13 Aug 2020 18:42:42

US3862007

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'un UNK 2015'	Carrie Kibler (b) (4)	13 Aug 2020 18:43:33
DataPoint activated with code reason code Data required.	(b) (4)	13 Aug 2020 18:43:03
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	13 Aug 2020 18:42:42

US3862007

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4)	13 Aug 2020 18:43:33
DataPoint activated with code reason code Data required.	(b) (4)	
	Carrie Kibler (b) (4)	13 Aug 2020 18:43:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Carrie Kibler (b) (4)	13 Aug 2020 18:42:42
	(b) (4)	

US3862007

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	13 Aug 2020 18:43:33
DataPoint activated with code reason code Data required.	(b) (4)	
	Carrie Kibler (b) (4)	13 Aug 2020 18:43:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Carrie Kibler (b) (4)	13 Aug 2020 18:42:42
	(b) (4)	

US3862007

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 18:43:33
DataPoint activated with code reason code Data required.	(b) (4)	
	Carrie Kibler (b) (4)	13 Aug 2020 18:43:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Carrie Kibler (b) (4)	13 Aug 2020 18:42:42
	(b) (4)	

US3862007

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4)	13 Aug 2020 18:43:33
DataPoint activated with code reason code Data required.	(b) (4)	
	Carrie Kibler (b) (4)	13 Aug 2020 18:43:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Carrie Kibler (b) (4)	13 Aug 2020 18:42:42
	(b) (4)	

US3862007

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jan 2015'	System	13 Aug 2020 18:43:33
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	13 Aug 2020 18:43:03
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	13 Aug 2020 18:42:42

US3862007

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2015'	System	13 Aug 2020 18:43:33
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	13 Aug 2020 18:43:03
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	13 Aug 2020 18:42:42

US3862007

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	13 Aug 2020 18:43:33
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	13 Aug 2020 18:43:03
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	13 Aug 2020 18:42:42

US3862007

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	13 Aug 2020 18:43:33
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	13 Aug 2020 18:43:03
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	13 Aug 2020 18:42:42

US3862007

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 18:45:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 18:45:23
Data point term sent to Coder	System	13 Aug 2020 18:44:14
User entered 'hypothyroidism'	Carrie Kibler (b) (4)	13 Aug 2020 18:43:50

US3862007

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'un UNK 1985'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:43:50

US3862007

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:43:50

US3862007

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:43:50

US3862007

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:43:50

US3862007

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:43:50

US3862007

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jan 1985'	System	13 Aug 2020 18:43:50

US3862007

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '1985'	System	13 Aug 2020 18:43:50

US3862007

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	13 Aug 2020 18:43:50

US3862007

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	13 Aug 2020 18:43:50

US3862007

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:45:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:45:23
Data point term sent to Coder	System	13 Aug 2020 18:44:14
User entered 'constipation'	Carrie Kibler (b) (4)	13 Aug 2020 18:44:03

US3862007

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'un UNK 2017'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:03

US3862007

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:03

US3862007

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:03

US3862007

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:03

US3862007

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:03

US3862007

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jan 2017'	System	13 Aug 2020 18:44:03

US3862007

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2017'	System	13 Aug 2020 18:44:03

US3862007

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	13 Aug 2020 18:44:03

US3862007

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	13 Aug 2020 18:44:03

US3862007

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:46:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:46:20
Data point term sent to Coder	System	13 Aug 2020 18:45:17
User entered 'Seasonal allergies'	Carrie Kibler (b) (4)	13 Aug 2020 18:44:18

US3862007

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'un UNK 2018'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:18

US3862007

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:18

US3862007

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:18

US3862007

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:18

US3862007

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:18

US3862007

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jan 2018'	System	13 Aug 2020 18:44:18

US3862007

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2018'	System	13 Aug 2020 18:44:18

US3862007

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	13 Aug 2020 18:44:18

US3862007

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	13 Aug 2020 18:44:18

US3862007

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User coded data point as SOC: Vascular disorders, HLT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Tibial vein thrombosis - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 20:42:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 20:42:12
Data point term sent to Coder	System	13 Aug 2020 18:45:17
User entered 'Anterior Tibial Vein Thrombosis'	Carrie Kibler (b) (4)	13 Aug 2020 18:44:40

US3862007

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '20 Feb 2020'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:40

US3862007

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:40

US3862007

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Aug 2020 18:46:38
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	13 Aug 2020 18:44:40

US3862007

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'un Jun 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Aug 2020 18:46:38
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 18:44:40

US3862007

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:40

US3862007

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Feb 2020'	System	13 Aug 2020 18:44:40

US3862007

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2020'	System	13 Aug 2020 18:44:40

US3862007

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jun 2020'	System	13 Aug 2020 18:46:38
User entered empty.	System	13 Aug 2020 18:44:40

US3862007

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2020'	System	13 Aug 2020 18:46:38
User entered empty.	System	13 Aug 2020 18:44:40

US3862007

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Genital herpes, LLT: Genital herpes - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 18:34:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 18:34:40
Data point term sent to Coder	System	29 Sep 2020 18:33:48
Coding entries removed.	Coni Cheesman (b) (4)	29 Sep 2020 18:33:36
User entered 'GENITAL HERPES' reason for change: Data Entry Error	Coni Cheesman (b) (4)	29 Sep 2020 18:33:36
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Genital herpes, LLT: Genital herpes - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 09:18:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 09:18:14
Data point term sent to Coder	System	13 Aug 2020 18:45:18
User entered 'genital herpes'	Carrie Kibler (b) (4)	13 Aug 2020 18:44:54

US3862007

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'un UNK 1987'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:54

US3862007

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:54

US3862007

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:54

US3862007

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:54

US3862007

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:44:54

US3862007

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jan 1987'	System	13 Aug 2020 18:44:54

US3862007

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '1987'	System	13 Aug 2020 18:44:54

US3862007

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	13 Aug 2020 18:44:54

US3862007

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	13 Aug 2020 18:44:54

US3862007

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 18:43:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 18:43:32
Data point term sent to Coder	System	13 Aug 2020 18:42:09
User entered 'Obstructive sleep apnea'	Carrie Kibler (b) (4)	13 Aug 2020 18:41:18

US3862007

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'un Mar 2012'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:41:18

US3862007

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:41:18

US3862007

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:41:18

US3862007

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:41:18

US3862007

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:41:18

US3862007

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Mar 2012'	System	13 Aug 2020 18:41:18

US3862007

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2012'	System	13 Aug 2020 18:41:18

US3862007

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	13 Aug 2020 18:41:18

US3862007

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	13 Aug 2020 18:41:18

US3862007

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 18:26:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 18:26:42
Data point term sent to Coder	System	29 Sep 2020 18:25:23
User entered 'Osteoarthritis'	Coni Cheesman (b) (4)	29 Sep 2020 18:24:29

US3862007

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'UN UNK 1990'	Coni Cheesman (b) (4)	29 Sep 2020 18:24:29

US3862007

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	29 Sep 2020 18:24:29

US3862007

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	29 Sep 2020 18:24:29

US3862007

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Coni Cheesman (b) (4)	29 Sep 2020 18:24:29

US3862007

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	29 Sep 2020 18:24:29

US3862007

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jan 1990'	System	29 Sep 2020 18:24:29

US3862007

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '1990'	System	29 Sep 2020 18:24:29

US3862007

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	29 Sep 2020 18:24:29

US3862007

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	29 Sep 2020 18:24:29

US3862007

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 08:00:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 08:00:55
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 05:46:49
User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) of KNEE REPLACEMENT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 05:31:34
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 'No condition to update.' (Site from DM).	Shetel Anassi (b) (4)	02 Nov 2020 18:56:43
Data point term sent to Coder	System	02 Nov 2020 18:55:49
Query 'Per DM CLR: Please specify the location (bilateral, left, right) of KNEE REPLACEMENT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Data corrected' (Site from DM).	Shetel Anassi (b) (4)	02 Nov 2020 18:55:44
Coding entries removed.	Shetel Anassi (b) (4)	02 Nov 2020 18:55:31
User entered 'KNEE REPLACEMENT (left)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	02 Nov 2020 18:55:31

US3862007

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
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)	28 Oct 2020 18:48:42
User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) of KNEE REPLACEMENT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:48:25
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 18:27:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 18:27:45
Data point term sent to Coder	System	29 Sep 2020 18:26:25
User entered 'Knee replacement'	Coni Cheesman (b) (4)	29 Sep 2020 18:26:00

US3862007

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '16 Dec 2019'	Coni Cheesman (b) (4)	29 Sep 2020 18:26:00

US3862007

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	29 Sep 2020 18:26:00

US3862007

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	29 Sep 2020 18:26:00

US3862007

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '16 Dec 2019'	Coni Cheesman (b) (4)	29 Sep 2020 18:26:00

US3862007

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	29 Sep 2020 18:26:00

US3862007

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Dec 2019'	System	29 Sep 2020 18:26:00

US3862007

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2019'	System	29 Sep 2020 18:26:00

US3862007

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Dec 2019'	System	29 Sep 2020 18:26:00

US3862007

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2019'	System	29 Sep 2020 18:26:00

US3862007

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 03:46:41
User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) of TOTAL HIP REPLACEMENT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 05:32:17
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Total hip replacement - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 10:18:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 10:18:22
Query 'Per DM CLR: Please specify the location (bilateral, left, right) of TOTAL HIP REPLACEMENT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Data corrected' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	02 Nov 2020 18:58:14
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 'condition stated in MH' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	02 Nov 2020 18:58:06
Data point term sent to Coder Coding entries removed.	System Shetel Anassi (b) (4) (b) (4)	02 Nov 2020 18:57:50 02 Nov 2020 18:57:46
User entered 'TOTAL HIP REPLACEMENT (right)' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	02 Nov 2020 18:57:46

US3862007

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:06:10

[Condition](#)

Audit	User	Time (GMT)
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)	28 Oct 2020 18:49:16
User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) of TOTAL HIP REPLACEMENT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:49:05
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Total hip replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 18:28:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 18:28:35
Data point term sent to Coder	System	29 Sep 2020 18:27:28
User entered 'Total hip replacement'	Coni Cheesman (b) (4)	29 Sep 2020 18:26:47

US3862007

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'un Jan 2013'	Coni Cheesman (b) (4)	29 Sep 2020 18:26:47

US3862007

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	29 Sep 2020 18:26:47

US3862007

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	29 Sep 2020 18:26:47

US3862007

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'un Jan 2013'	Coni Cheesman (b) (4)	29 Sep 2020 18:26:47

US3862007

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	29 Sep 2020 18:26:47

US3862007

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jan 2013'	System	29 Sep 2020 18:26:47

US3862007

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2013'	System	29 Sep 2020 18:26:47

US3862007

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jan 2013'	System	29 Sep 2020 18:26:47

US3862007

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2013'	System	29 Sep 2020 18:26:47

US3862007

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
Query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition # 15 (TOTAL ABDOMINAL HYSTERECTOMY). If yes, please ensure only one entry is recorded. Otherwise, provide comment. ' canceled (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 03:13:12
User opened query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition # 15 (TOTAL ABDOMINAL HYSTERECTOMY). If yes, please ensure only one entry is recorded. Otherwise, provide comment. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 03:12:39
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total abdominal hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 10:27:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 10:27:58
User closed query 'Per DM CLR: Only one medical procedure should be entered per line. Please update MH term to indicate a single underlying procedure or split events and record them as a different procedure (MH# 18 and MH# 19). ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 09:03:12
Data point term sent to Coder	System	02 Nov 2020 19:00:56
Query 'Per DM CLR: Only one medical procedure should be entered per line. Please update MH term to indicate a single underlying procedure or split events and record them as a different procedure (MH# 18 and MH# 19). ' answered with 'Data corrected.' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	02 Nov 2020 19:00:45
Coding entries removed.	Shetel Anassi (b) (4) (b) (4)	02 Nov 2020 19:00:35
User entered 'TOTAL ABDOMINAL HYSTERECTOMY' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	02 Nov 2020 19:00:35

US3862007

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Only one medical procedure should be entered per line. Please update MH term to indicate a single underlying procedure or split events and record them as a different procedure (MH# 18 and MH# 19). ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:49:47
User coded data point as SOC: Surgical and medical procedures, HLG: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterosalpingo-oophorectomy, LLT: Total abdominal hysterectomy with bilateral salpingo-oophorectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 00:07:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 00:07:42
Data point term sent to Coder	System	29 Sep 2020 18:29:35
User entered 'Total abdominal hysterectomy and bilateral salpingo- oophorectomy'	Coni Cheesman (b) (4)	29 Sep 2020 18:28:57

US3862007

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Per CDM: Please consider updating to UN SEP 2006 as this is recorded on Childbearing form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 09:02:58
Query 'Per CDM: Please consider updating to UN SEP 2006 as this is recorded on Childbearing form. Thank you. ' answered with 'Data corrected' (Site from DM).	Shetel Anassi (b) (4)	26 Oct 2020 22:10:24
User entered 'UN Sep 2006' reason for change: Data Entry Error	Shetel Anassi (b) (4)	26 Oct 2020 22:10:07
User opened query 'Per CDM: Please consider updating to UN SEP 2006 as this is recorded on Childbearing form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 18:41:33
User entered 'un UNK 2006'	Coni Cheesman (b) (4)	29 Sep 2020 18:28:57

US3862007

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	29 Sep 2020 18:28:57

US3862007

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	29 Sep 2020 18:28:57

US3862007

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Per CDM: Please consider updating to UN SEP 2006 as this is recorded on Childbearing form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 09:03:00
Query 'Per CDM: Please consider updating to UN SEP 2006 as this is recorded on Childbearing form. Thank you. ' answered with 'Data Corrected' (Site from DM).	Shetel Anassi (b) (4)	26 Oct 2020 22:10:35
User entered 'UN Sep 2006' reason for change: Data Entry Error	Shetel Anassi (b) (4)	26 Oct 2020 22:10:07
User opened query 'Per CDM: Please consider updating to UN SEP 2006 as this is recorded on Childbearing form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 18:41:50
User entered 'un UNK 2006'	Coni Cheesman (b) (4)	29 Sep 2020 18:28:57

US3862007

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	29 Sep 2020 18:28:57

US3862007

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Sep 2006'	System	26 Oct 2020 22:10:07
User entered 'Jan 2006'	System	29 Sep 2020 18:28:57

US3862007

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2006'	System	29 Sep 2020 18:28:57

US3862007

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Sep 2006'	System	26 Oct 2020 22:10:07
User entered 'Jan 2006'	System	29 Sep 2020 18:28:57

US3862007

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2006'	System	29 Sep 2020 18:28:57

US3862007

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 18:32:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 18:32:49
Data point term sent to Coder	System	29 Sep 2020 18:31:44
User entered 'Thyroidectomy'	Coni Cheesman (b) (4)	29 Sep 2020 18:31:30

US3862007

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'un UNK 1985'	Coni Cheesman (b) (4)	29 Sep 2020 18:31:30

US3862007

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	29 Sep 2020 18:31:30

US3862007

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	29 Sep 2020 18:31:30

US3862007

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'un UNK 1985'	Coni Cheesman (b) (4)	29 Sep 2020 18:31:30

US3862007

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	29 Sep 2020 18:31:30

US3862007

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jan 1985'	System	29 Sep 2020 18:31:30

US3862007

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '1985'	System	29 Sep 2020 18:31:30

US3862007

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jan 1985'	System	29 Sep 2020 18:31:30

US3862007

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '1985'	System	29 Sep 2020 18:31:30

US3862007

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User closed query 'Per Medical Records, Please consider adding Morbid Obesity, HTN, CKD Stage 2, anemia, hemorrhoids, gestational diabetes, thyroid cancer, Omalizumab Allergy, C-section to Med HX. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 17:21:33
Query 'Per Medical Records, Please consider adding Morbid Obesity, HTN, CKD Stage 2, anemia, hemorrhoids, gestational diabetes, thyroid cancer, Omalizumab Allergy, C-section to Med HX. ' answered with 'UPDATED IN SOURCE DOCUMNT AND EDC' (Site from CRA).	Thea Marie Cordero (b) (4)	21 Apr 2021 20:28:48
User opened query 'Per Medical Records, Please consider adding Morbid Obesity, HTN, CKD Stage 2, anemia, hemorrhoids, gestational diabetes, thyroid cancer, Omalizumab Allergy, C-section to Med HX. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 21:20:10
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Fallopian tube therapeutic procedures, PT: Salpingo-oophorectomy bilateral, LLT: Bilateral salpingo-oophorectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 10:33:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 10:33:42
Data point term sent to Coder	System	02 Nov 2020 19:02:59
User entered 'bilateral salpingo-oophorectomy'	Shetel Anassi (b) (4) (b) (4)	02 Nov 2020 19:02:32

US3862007

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'un UNK 2006'	Shetel Anassi (b) (4) (b) (4)	02 Nov 2020 19:02:32

US3862007

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Shetel Anassi (b) (4) (b) (4)	02 Nov 2020 19:02:32

US3862007

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Shetel Anassi (b) (4) (b) (4)	02 Nov 2020 19:02:32

US3862007

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'un UNK 2006'	Shetel Anassi (b) (4) (b) (4)	02 Nov 2020 19:02:32

US3862007

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Shetel Anassi (b) (4) (b) (4)	02 Nov 2020 19:02:32

US3862007

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jan 2006'	System	02 Nov 2020 19:02:32

US3862007

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2006'	System	02 Nov 2020 19:02:32

US3862007

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jan 2006'	System	02 Nov 2020 19:02:32

US3862007

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2006'	System	02 Nov 2020 19:02:32

US3862007

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:06:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Iron deficiency anemia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 20:02:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 20:02:06
Data point term sent to Coder	System	21 Apr 2021 19:10:28
User entered 'IRON DEFICIENCY ANEMIA'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:10:17

US3862007

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'UN Sep 2017'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:10:17

US3862007

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered '0'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:10:17

US3862007

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'No (N)'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:10:17

US3862007

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'UN Dec 2017'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:10:17

US3862007

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered '0'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:10:17

US3862007

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Sep 2017'	System	21 Apr 2021 19:10:17

US3862007

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2017'	System	21 Apr 2021 19:10:17

US3862007

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Dec 2017'	System	21 Apr 2021 19:10:17

US3862007

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2017'	System	21 Apr 2021 19:10:17

US3862007

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids thrombosed, LLT: External thrombosed hemorrhoids - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 06:33:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 06:33:52
Data point term sent to Coder	System	21 Apr 2021 19:16:33
User entered 'EXTERNAL THROMOBOSED HEMORRHIDS'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:15:59

US3862007

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'UN Jun 2009'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:15:59

US3862007

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered '0'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:15:59

US3862007

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'No (N)'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:15:59

US3862007

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'UN Jul 2009'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:15:59

US3862007

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:06:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered '0'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:15:59

US3862007

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jun 2009'	System	21 Apr 2021 19:15:59

US3862007

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2009'	System	21 Apr 2021 19:15:59

US3862007

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jul 2009'	System	21 Apr 2021 19:15:59

US3862007

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2009'	System	21 Apr 2021 19:15:59

US3862007

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLG: Maternal complications of pregnancy, HLT: Pregnancy complicated by maternal disorders, PT: Gestational diabetes, LLT: Gestational diabetes - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 20:02:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 20:02:48
Data point term sent to Coder	System	21 Apr 2021 19:19:38
User entered 'GESTATIONAL DIABETES'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:19:09

US3862007

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'UN Jun 1983'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:19:09

US3862007

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered '0'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:19:09

US3862007

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'No (N)'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:19:09

US3862007

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'UN Dec 1983'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:19:09

US3862007

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered '0'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:19:09

US3862007

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jun 1983'	System	21 Apr 2021 19:19:09

US3862007

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '1983'	System	21 Apr 2021 19:19:09

US3862007

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Dec 1983'	System	21 Apr 2021 19:19:09

US3862007

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '1983'	System	21 Apr 2021 19:19:09

US3862007

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:06:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 20:03:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 20:03:15
Data point term sent to Coder	System	21 Apr 2021 19:20:39
User entered 'CESARIAN SECTION'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:19:58

US3862007

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'UN Dec 1983'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:19:58

US3862007

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered '0'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:19:58

US3862007

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'No (N)'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:19:58

US3862007

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'UN Dec 1983'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:19:58

US3862007

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered '0'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:19:58

US3862007

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Dec 1983'	System	21 Apr 2021 19:19:58

US3862007

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '1983'	System	21 Apr 2021 19:19:58

US3862007

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Dec 1983'	System	21 Apr 2021 19:19:58

US3862007

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '1983'	System	21 Apr 2021 19:19:58

US3862007

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:06:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User coded data point as SOC: Surgical and medical procedures, HLG: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 20:03:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 20:03:15
Data point term sent to Coder	System	21 Apr 2021 19:21:40
User entered 'CESARIAN SECTION'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:21:11

US3862007

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'UN Dec 1995'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:21:11

US3862007

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered '0'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:21:11

US3862007

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'No (N)'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:21:11

US3862007

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'UN Dec 1995'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:21:11

US3862007

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:06:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered '0'	Thea Marie Cordero (b) (4)	21 Apr 2021 19:21:11

US3862007

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Dec 1995'	System	21 Apr 2021 19:21:11

US3862007

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '1995'	System	21 Apr 2021 19:21:11

US3862007

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Dec 1995'	System	21 Apr 2021 19:21:11

US3862007

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '1995'	System	21 Apr 2021 19:21:11

US3862007

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 20:29:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 20:29:37
Data point term sent to Coder	System	21 Apr 2021 20:28:20
User entered 'OBESITY'	Thea Marie Cordero (b) (4)	21 Apr 2021 20:27:28

US3862007

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'UN Jan 1984'	Thea Marie Cordero (b) (4)	21 Apr 2021 20:27:28

US3862007

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered '0'	Thea Marie Cordero (b) (4)	21 Apr 2021 20:27:28

US3862007

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	21 Apr 2021 20:27:28

US3862007

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered empty.	Thea Marie Cordero (b) (4)	21 Apr 2021 20:27:28

US3862007

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:06:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered '0'	Thea Marie Cordero (b) (4)	21 Apr 2021 20:27:28

US3862007

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Jan 1984'	System	21 Apr 2021 20:27:28

US3862007

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '1984'	System	21 Apr 2021 20:27:28

US3862007

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	21 Apr 2021 20:27:28

US3862007

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	21 Apr 2021 20:27:28

US3862007

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:06:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 20:29:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 20:29:37
Data point term sent to Coder	System	21 Apr 2021 20:28:20
User entered 'OSTEOPENIA'	Thea Marie Cordero (b) (4)	21 Apr 2021 20:28:01

US3862007

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered '01 Sep 2016'	Thea Marie Cordero (b) (4)	21 Apr 2021 20:28:01

US3862007

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered '0'	Thea Marie Cordero (b) (4)	21 Apr 2021 20:28:01

US3862007

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:06:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	21 Apr 2021 20:28:01

US3862007

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered empty.	Thea Marie Cordero (b) (4)	21 Apr 2021 20:28:01

US3862007

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:06:10

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:21
User entered '0'	Thea Marie Cordero (b) (4)	21 Apr 2021 20:28:01

US3862007

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:06:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'Sep 2016'	System	21 Apr 2021 20:28:01

US3862007

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:06:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '2016'	System	21 Apr 2021 20:28:01

US3862007

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	21 Apr 2021 20:28:01

US3862007

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered empty.	System	21 Apr 2021 20:28:01

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 16:35:48

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '13 Aug 2020'	Coni Cheesman (b) (4)	13 Aug 2020 16:35:48

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '10:30'	Coni Cheesman (b) (4)	13 Aug 2020 16:35:48

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '13 Aug 2020 10:30'	System	13 Aug 2020 16:35:48

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '64.0' in	Coni Cheesman (b) (4)	13 Aug 2020 16:35:48
DataPoint set to visible.	System	13 Aug 2020 16:33:05

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '224.6' lb	Coni Cheesman (b) (4)	13 Aug 2020 16:35:48
DataPoint set to visible.	System	13 Aug 2020 16:33:05

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
Amendment Manager: User entered '38.63311'	System	16 Sep 2020 23:55:27
User entered '38.6'	System	13 Aug 2020 16:35:48
DataPoint set to visible.	System	13 Aug 2020 16:33:05

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'kg/m2'	System	13 Aug 2020 16:35:48
DataPoint set to visible.	System	13 Aug 2020 16:33:05

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Per CDM: Per CCGs, please record ND in applicable data-fields (for Temperature, Pulse, Respiratory Rate, Systolic BP, and Diastolic BP)since Subject was screened and dosed on the same day and duplicate data has been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 11:39:11
Query 'Per CDM: Per CCGs, please record ND in applicable data-fields (for Temperature, Pulse, Respiratory Rate, Systolic BP, and Diastolic BP)since Subject was screened and dosed on the same day and duplicate data has been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Thank you.' answered with 'corrected' (Site from DM).	Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 19:01:04
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 19:00:50
User opened query 'Per CDM: Per CCGs, please record ND in applicable data-fields (for Temperature, Pulse, Respiratory Rate, Systolic BP, and Diastolic BP)since Subject was screened and dosed on the same day and duplicate data has been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 17:14:05
User entered '98.0' F	Coni Cheesman (b) (4)	13 Aug 2020 16:35:48

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty; reason for change Per Query Resolution	Carrie Kibler (b) (4)	16 Oct 2020 19:00:50
User entered 'Other (Other)'	(b) (4)	
	Coni Cheesman (b) (4)	13 Aug 2020 16:35:48

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty; reason for change Per Query Resolution	Carrie Kibler (b) (4)	16 Oct 2020 19:00:50
User entered 'Temporal'	Coni Cheesman (b) (4)	13 Aug 2020 16:35:48

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carrie Kibler (b) (4)	16 Oct 2020 19:00:50
User entered '65'	(b) (4)	
	Coni Cheesman (b) (4)	13 Aug 2020 16:35:48

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
Query 'Per CDM: Please consider removing 'Pulse units- BPM ', 'Respiratory Rate units-BREATHS/MIN ', 'Systolic BP units- MMHG ' and 'Diastolic BP units- MMHG' and leave blank for these 'units' fields only.' canceled (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 20:23:32
User opened query 'Per CDM: Please consider removing 'Pulse units- BPM ', 'Respiratory Rate units-BREATHS/MIN ', 'Systolic BP units- MMHG ' and 'Diastolic BP units- MMHG' and leave blank for these 'units' fields only.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 11:39:34
User entered 'bpm'	System	13 Aug 2020 16:35:48

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carrie Kibler (b) (4)	16 Oct 2020 19:00:50
User entered '16'	(b) (4)	
	Coni Cheesman (b) (4)	13 Aug 2020 16:35:48

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'breaths/min'	System	13 Aug 2020 16:35:48

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carrie Kibler (b) (4)	16 Oct 2020 19:00:50
User entered '130'	(b) (4)	
	Coni Cheesman (b) (4)	13 Aug 2020 16:35:48

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'mmHg'	System	13 Aug 2020 16:35:48

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carrie Kibler (b) (4)	16 Oct 2020 19:00:50
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 11:20:46
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	Trent Davis (b) (4)	23 Sep 2020 19:04:08
User entered '57'	(b) (4)	
	System	16 Sep 2020 23:55:27
	Coni Cheesman (b) (4)	13 Aug 2020 16:35:48

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'mmHg'	System	13 Aug 2020 16:35:48

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28

US3862007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28

US3862007

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:10

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 16:36:08

US3862007

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 18:55:31
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 21:21:01
User entered '13 Aug 2020'	Coni Cheesman (b) (4)	13 Aug 2020 16:36:08

US3862007

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '13 Aug 2020'	Coni Cheesman (b) (4)	13 Aug 2020 16:36:54

US3862007

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:06:10

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:36:54

US3862007

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:06:10

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 18:37:39
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. '(Site from DM).	(b) (4), (b) (6)	01 Oct 2020 05:26:28
User entered 'Surgically sterile (SURGICALLY STERILE)'	Coni Cheesman (b) (4)	13 Aug 2020 16:36:54

US3862007

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:06:10

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 16:36:54

US3862007

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:06:10

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'UN Sep 2006'	Coni Cheesman (b) (4)	13 Aug 2020 16:36:54

US3862007

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:06:10

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 16:36:54

US3862007

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 16:36:54

US3862007

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:06:10

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 16:36:54

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0' reason for change: Data Entry Error	Carrie Kibler (b) (4)	06 Oct 2020 20:29:47
User entered '1'	(b) (4) Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '1' reason for change: Data Entry Error	Carrie Kibler (b) (4)	06 Oct 2020 20:29:47
User entered '0'	(b) (4) Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 16:38:14

US3862007

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 16:40:45

US3862007

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '13 Aug 2020'	Coni Cheesman (b) (4)	13 Aug 2020 16:40:45

US3862007

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Clinic (Clinic)'	Coni Cheesman (b) (4)	13 Aug 2020 16:40:45

US3862007

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'VISIT1'	System	13 Aug 2020 16:40:45

US3862007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:44:45

US3862007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:06:10

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:12:20
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:12:20
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 16:44:45
User entered '185289' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:44:45

US3862007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:06:10

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:44:45

US3862007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:06:10

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:50:56

US3862007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:06:10

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:50:56

US3862007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:06:10

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:50:56

US3862007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:06:10

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 16:50:56

US3862007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:06:10

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:50:56

US3862007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:06:10

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Trent Davis (b) (4)	23 Sep 2020 18:55:24
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:19:48
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:02:40

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:06:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carrie Kibler (b) (4)	16 Oct 2020 19:01:28
User entered '64' in	(b) (4) Coni Cheesman (b) (4)	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:06:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carrie Kibler (b) (4)	16 Oct 2020 19:01:28
User entered '224.6' lb	(b) (4) Coni Cheesman (b) (4)	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:06:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carrie Kibler (b) (4)	16 Oct 2020 19:01:28
User entered '64' in	(b) (4) Coni Cheesman (b) (4)	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:06:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carrie Kibler (b) (4)	16 Oct 2020 19:01:28
User entered '224.6' lb	(b) (4) Coni Cheesman (b) (4)	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User accepted default value 'Pre-Dose (PREDOSE)'	Coni Cheesman (b) (4)	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '13 Aug 2020'	Coni Cheesman (b) (4)	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '10:30'	Coni Cheesman (b) (4)	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered '13 Aug 2020 10:30'	System	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '98.0' F	Coni Cheesman (b) (4)	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Other (Other)'	Coni Cheesman (b) (4)	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Temporal'	Coni Cheesman (b) (4)	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '65'	Coni Cheesman (b) (4)	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'bpm'	System	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '16'	Coni Cheesman (b) (4)	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'breaths/min'	System	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '130'	Coni Cheesman (b) (4)	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'mmHg'	System	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 11:22:13
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Trent Davis (b) (4) (b) (4)	23 Sep 2020 18:53:56
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:55:27
User entered '57'	Coni Cheesman (b) (4)	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'mmHg'	System	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:06:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carrie Kibler (b) (4)	16 Oct 2020 19:01:28
User entered '64' in	(b) (4) Coni Cheesman (b) (4)	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:06:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carrie Kibler (b) (4)	16 Oct 2020 19:01:28
User entered '224.6' lb	(b) (4) Coni Cheesman (b) (4)	13 Aug 2020 16:52:47

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User accepted default value 'Post-Dose (POSTDOSE)'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:49:40

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:49:40

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '13 Aug 2020'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:49:40

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 13:42:08
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Please refer to protocol section 8.2.5 that "vital sign measurements will be collected...at least 30 minutes after IP injection."' (Site from System).	Carrie Kibler (b) (4)	13 Aug 2020 18:52:21
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		13 Aug 2020 18:49:40
User entered '13:00'	Carrie Kibler (b) (4)	13 Aug 2020 18:49:40

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered '13 Aug 2020 13:00'	System	13 Aug 2020 18:49:40

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '97.8' F	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:49:40

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	13 Aug 2020 18:51:36
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	13 Aug 2020 18:49:40
User entered 'Other (Other)'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:49:40

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'temporal' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Aug 2020 18:51:36
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	13 Aug 2020 18:49:40
	(b) (4)	

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 18:51:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Aug 2020 18:51:36
User entered '72' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Aug 2020 18:51:36
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 18:49:40
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 18:49:40
	(b) (4)	

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'bpm'	System	13 Aug 2020 18:51:36
User entered empty.	System	13 Aug 2020 18:49:40

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 18:51:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Aug 2020 18:51:36
User entered '16' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Aug 2020 18:51:36
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 18:49:40
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 18:49:40
	(b) (4)	

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'breaths/min'	System	13 Aug 2020 18:51:36
User entered empty.	System	13 Aug 2020 18:49:40

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 18:51:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Aug 2020 18:51:36
User entered '115' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Aug 2020 18:51:36
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 18:49:40
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 18:49:40
	(b) (4)	

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'mmHg'	System	13 Aug 2020 18:51:36
User entered empty.	System	13 Aug 2020 18:49:40

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 18:51:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Aug 2020 18:51:36
User entered '69' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Aug 2020 18:51:36
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 18:49:40
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 18:49:40
	(b) (4)	

US3862007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'mmHg'	System	13 Aug 2020 18:51:36
User entered empty.	System	13 Aug 2020 18:49:40

US3862007

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:10

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 16:53:34

US3862007

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '13 Aug 2020'	Coni Cheesman (b) (4)	13 Aug 2020 16:53:34

US3862007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 18:02:07

US3862007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 18:02:07

US3862007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 18:02:07

US3862007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 18:02:07

US3862007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '13 Aug 2020'	Coni Cheesman (b) (4)	13 Aug 2020 18:02:07

US3862007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '12:29'	Coni Cheesman (b) (4)	13 Aug 2020 18:02:07

US3862007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered '13 Aug 2020 12:29'	System	13 Aug 2020 18:02:07

US3862007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Left Arm (LEFT ARM)'	Coni Cheesman (b) (4)	13 Aug 2020 18:02:07

US3862007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'ONCE'	System	13 Aug 2020 18:02:07

US3862007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 18:02:07

US3862007

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 16:56:15

US3862007

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '13 Aug 2020'	Coni Cheesman (b) (4)	13 Aug 2020 16:56:15

US3862007

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '11:23'	Coni Cheesman (b) (4)	13 Aug 2020 16:56:15

US3862007

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered '13 Aug 2020 11:23'	System	13 Aug 2020 16:56:15

US3862007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:06:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '13 Aug 2020'	Coni Cheesman (b) (4)	13 Aug 2020 16:55:09

US3862007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:06:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Coni Cheesman (b) (4)	13 Aug 2020 16:55:09

US3862007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 16:55:09

US3862007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:06:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '11:02' reason for change: New Information	Coni Cheesman (b) (4)	13 Aug 2020 16:56:53
User entered '10:45'	Coni Cheesman (b) (4)	13 Aug 2020 16:55:09

US3862007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:06:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered '13 Aug 2020 11:02'	System	13 Aug 2020 16:56:53
User entered '13 Aug 2020 10:45'	System	13 Aug 2020 16:55:09

US3862007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:06:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Coni Cheesman (b) (4)	13 Aug 2020 16:55:09

US3862007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 16:55:09

US3862007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:06:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 16:55:09

US3862007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:06:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered empty.	System	13 Aug 2020 16:55:09

US3862007

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	20 Aug 2020 22:58:08

US3862007

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered '1'	System	20 Aug 2020 22:58:08

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T13:05:40', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5aa025cb-b4ab-4165-aa84-d2b52b040af6'	System	13 Aug 2020 18:05:59
User entered 'Yes (Y)'	System	13 Aug 2020 18:05:59

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T13:05:46', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5aa025cb-b4ab-4165-aa84-d2b52b040af6'	System	13 Aug 2020 18:05:59
User entered '97.8'	System	13 Aug 2020 18:05:59

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T13:05:52', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5aa025cb-b4ab-4165-aa84-d2b52b040af6'	System	13 Aug 2020 18:05:59
User entered 'No (N)'	System	13 Aug 2020 18:05:59

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T13:05:56', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5aa025cb-b4ab-4165-aa84-d2b52b040af6'	System	13 Aug 2020 18:05:59
User entered '13 Aug 2020 13:05'	System	13 Aug 2020 18:05:59

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '13 Aug 2020 12:49'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '13 Aug 2020 15:19'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T21:00:44', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f0c8997a-c16f-44ef-b283-ece2a91a0e61'	System	14 Aug 2020 02:01:06
User entered 'Yes (Y)'	System	14 Aug 2020 02:01:06

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T21:00:50', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f0c8997a-c16f-44ef-b283-ece2a91a0e61'	System	14 Aug 2020 02:01:06
User entered '98.0'	System	14 Aug 2020 02:01:06

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T21:00:56', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f0c8997a-c16f-44ef-b283-ece2a91a0e61'	System	14 Aug 2020 02:01:06
User entered 'No (N)'	System	14 Aug 2020 02:01:06

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T21:01:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f0c8997a-c16f-44ef-b283-ece2a91a0e61'	System	14 Aug 2020 02:01:06
User entered '13 Aug 2020 21:01'	System	14 Aug 2020 02:01:06

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '13 Aug 2020 16:14'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 2'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-14T22:19:54', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '57d73997-2ed7-4630-b0aa-f5c65d3930d9'	System	15 Aug 2020 03:20:18
User entered 'Yes (Y)'	System	15 Aug 2020 03:20:18

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-14T22:20:06', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '57d73997-2ed7-4630-b0aa-f5c65d3930d9'	System	15 Aug 2020 03:20:18
User entered '96.7'	System	15 Aug 2020 03:20:18

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-14T22:20:12', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '57d73997-2ed7-4630-b0aa-f5c65d3930d9'	System	15 Aug 2020 03:20:18
User entered 'No (N)'	System	15 Aug 2020 03:20:18

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-14T22:20:16', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '57d73997-2ed7-4630-b0aa-f5c65d3930d9'	System	15 Aug 2020 03:20:18
User entered '14 Aug 2020 22:20'	System	15 Aug 2020 03:20:18

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 3'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T00:22:12', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'b10159c7-3ecf-4efb-9d95-515b766b4a32'	System	16 Aug 2020 05:22:27
User entered 'Yes (Y)'	System	16 Aug 2020 05:22:27

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T00:22:17', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'b10159c7-3ecf-4efb-9d95-515b766b4a32'	System	16 Aug 2020 05:22:27
User entered '98.3'	System	16 Aug 2020 05:22:27

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T00:22:20', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'b10159c7-3ecf-4efb-9d95-515b766b4a32'	System	16 Aug 2020 05:22:27
User entered 'No (N)'	System	16 Aug 2020 05:22:27

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T00:22:24', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'b10159c7-3ecf-4efb-9d95-515b766b4a32'	System	16 Aug 2020 05:22:27
User entered '16 Aug 2020 00:22'	System	16 Aug 2020 05:22:27

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 4'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T21:36:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '3b13901a-a431-43ab-9e48-1b65c3014af0'	System	17 Aug 2020 02:37:17
User entered 'Yes (Y)'	System	17 Aug 2020 02:37:17

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T21:37:09', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '3b13901a-a431-43ab-9e48-1b65c3014af0'	System	17 Aug 2020 02:37:17
User entered '97.9'	System	17 Aug 2020 02:37:17

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T21:37:12', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '3b13901a-a431-43ab-9e48-1b65c3014af0'	System	17 Aug 2020 02:37:17
User entered 'No (N)'	System	17 Aug 2020 02:37:17

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T21:37:15', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '3b13901a-a431-43ab-9e48-1b65c3014af0'	System	17 Aug 2020 02:37:17
User entered '16 Aug 2020 21:37'	System	17 Aug 2020 02:37:17

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 5'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-17T23:01:43', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'dbe55deb-53d8-4807-b2bf-7e880998aac9'	System	18 Aug 2020 04:02:08
User entered 'Yes (Y)'	System	18 Aug 2020 04:02:08

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-17T23:01:48', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'dbe55deb-53d8-4807-b2bf-7e880998aac9'	System	18 Aug 2020 04:02:08
User entered '98.8'	System	18 Aug 2020 04:02:08

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-17T23:01:51', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'dbe55deb-53d8-4807-b2bf-7e880998aac9'	System	18 Aug 2020 04:02:08
User entered 'No (N)'	System	18 Aug 2020 04:02:08

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-17T23:01:55', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'dbe55deb-53d8-4807-b2bf-7e880998aac9'	System	18 Aug 2020 04:02:08
User entered '17 Aug 2020 23:01'	System	18 Aug 2020 04:02:08

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 6'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-18T21:21:19', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5bc611ef-98d1-43ce-ab62-2e5fe7bbe9e2'	System	19 Aug 2020 02:21:32
User entered 'Yes (Y)'	System	19 Aug 2020 02:21:32

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-18T21:21:24', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5bc611ef-98d1-43ce-ab62-2e5fe7bbe9e2'	System	19 Aug 2020 02:21:32
User entered '98.4'	System	19 Aug 2020 02:21:32

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-18T21:21:27', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5bc611ef-98d1-43ce-ab62-2e5fe7bbe9e2'	System	19 Aug 2020 02:21:32
User entered 'No (N)'	System	19 Aug 2020 02:21:32

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-18T21:21:30', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5bc611ef-98d1-43ce-ab62-2e5fe7bbe9e2'	System	19 Aug 2020 02:21:32
User entered '18 Aug 2020 21:21'	System	19 Aug 2020 02:21:32

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 7'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-20T11:46:55', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '91266e89-7034-4e3f-94d3-eb0bbe141831'	System	20 Aug 2020 16:47:10
User entered 'Yes (Y)'	System	20 Aug 2020 16:47:10

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-20T11:47:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '91266e89-7034-4e3f-94d3-eb0bbe141831'	System	20 Aug 2020 16:47:10
User entered '98.7'	System	20 Aug 2020 16:47:10

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-20T11:47:03', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '91266e89-7034-4e3f-94d3-eb0bbe141831'	System	20 Aug 2020 16:47:10
User entered 'No (N)'	System	20 Aug 2020 16:47:10

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-20T11:47:07', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '91266e89-7034-4e3f-94d3-eb0bbe141831'	System	20 Aug 2020 16:47:10
User entered '20 Aug 2020 11:47'	System	20 Aug 2020 16:47:10

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T13:06:02', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '16e84cc9-2bf6-48ff-bc79-82e957a164fc'	System	13 Aug 2020 18:06:28
User entered 'None (1)'	System	13 Aug 2020 18:06:28

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T13:06:07', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '16e84cc9-2bf6-48ff-bc79-82e957a164fc'	System	13 Aug 2020 18:06:28
User entered 'No (N)'	System	13 Aug 2020 18:06:28

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T13:06:10', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '16e84cc9-2bf6-48ff-bc79-82e957a164fc'	System	13 Aug 2020 18:06:28
User entered 'No (N)'	System	13 Aug 2020 18:06:28

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T13:06:16', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '16e84cc9-2bf6-48ff-bc79-82e957a164fc'	System	13 Aug 2020 18:06:28
User entered 'None (1)'	System	13 Aug 2020 18:06:28

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T13:06:25', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '16e84cc9-2bf6-48ff-bc79-82e957a164fc'	System	13 Aug 2020 18:06:28
User entered '13 Aug 2020 13:06'	System	13 Aug 2020 18:06:28

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '13 Aug 2020 12:49'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '13 Aug 2020 15:19'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T21:01:12', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '60587bee-7e3e-49a9-8795-d3e9944bc562'	System	14 Aug 2020 02:04:02
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 02:04:02

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T21:02:29', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '60587bee-7e3e-49a9-8795-d3e9944bc562'	System	14 Aug 2020 02:04:02
User entered 'No (N)'	System	14 Aug 2020 02:04:02

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T21:03:10', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '60587bee-7e3e-49a9-8795-d3e9944bc562'	System	14 Aug 2020 02:04:02
User entered 'No (N)'	System	14 Aug 2020 02:04:02

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T21:03:51', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '60587bee-7e3e-49a9-8795-d3e9944bc562'	System	14 Aug 2020 02:04:02
User entered 'None (1)'	System	14 Aug 2020 02:04:02

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T21:04:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '60587bee-7e3e-49a9-8795-d3e9944bc562'	System	14 Aug 2020 02:04:02
User entered '13 Aug 2020 21:04'	System	14 Aug 2020 02:04:02

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '13 Aug 2020 16:14'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 2'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-14T22:25:01', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'ab06093c-5229-481e-80c2-ab73250ce07e'	System	15 Aug 2020 03:25:17
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 03:25:17

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-14T22:25:05', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'ab06093c-5229-481e-80c2-ab73250ce07e'	System	15 Aug 2020 03:25:17
User entered 'No (N)'	System	15 Aug 2020 03:25:17

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-14T22:25:07', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'ab06093c-5229-481e-80c2-ab73250ce07e'	System	15 Aug 2020 03:25:17
User entered 'No (N)'	System	15 Aug 2020 03:25:17

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-14T22:25:11', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'ab06093c-5229-481e-80c2-ab73250ce07e'	System	15 Aug 2020 03:25:17
User entered 'None (1)'	System	15 Aug 2020 03:25:17

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-14T22:25:15', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'ab06093c-5229-481e-80c2-ab73250ce07e'	System	15 Aug 2020 03:25:17
User entered '14 Aug 2020 22:25'	System	15 Aug 2020 03:25:17

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 3'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T00:22:31', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '1cfeb2ab-87ba-472e-bb0b-3d502b78dceb'	System	16 Aug 2020 05:23:17
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 05:23:17

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T00:22:35', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '1cfeb2ab-87ba-472e-bb0b-3d502b78dceb'	System	16 Aug 2020 05:23:17
User entered 'No (N)'	System	16 Aug 2020 05:23:17

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T00:22:37', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '1cfeb2ab-87ba-472e-bb0b-3d502b78dceb'	System	16 Aug 2020 05:23:17
User entered 'No (N)'	System	16 Aug 2020 05:23:17

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T00:23:07', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '1cfeb2ab-87ba-472e-bb0b-3d502b78dceb'	System	16 Aug 2020 05:23:17
User entered 'None (1)'	System	16 Aug 2020 05:23:17

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T00:23:15', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '1cfeb2ab-87ba-472e-bb0b-3d502b78dceb'	System	16 Aug 2020 05:23:17
User entered '16 Aug 2020 00:23'	System	16 Aug 2020 05:23:17

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 4'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T21:37:22', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '2b09bec0-f9a3-44dd-934c-fcdc4f4000b3'	System	17 Aug 2020 02:37:36
User entered 'None (1)'	System	17 Aug 2020 02:37:36

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T21:37:25', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '2b09bec0-f9a3-44dd-934c-fcdc4f4000b3'	System	17 Aug 2020 02:37:36
User entered 'No (N)'	System	17 Aug 2020 02:37:36

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T21:37:27', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '2b09bec0-f9a3-44dd-934c-fcdc4f4000b3'	System	17 Aug 2020 02:37:36
User entered 'No (N)'	System	17 Aug 2020 02:37:36

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T21:37:31', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '2b09bec0-f9a3-44dd-934c-fcdc4f4000b3'	System	17 Aug 2020 02:37:36
User entered 'None (1)'	System	17 Aug 2020 02:37:36

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T21:37:33', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '2b09bec0-f9a3-44dd-934c-fcdc4f4000b3'	System	17 Aug 2020 02:37:36
User entered '16 Aug 2020 21:37'	System	17 Aug 2020 02:37:36

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 5'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-17T23:02:08', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c47f22c3-f4ca-471f-8aab-d43587601914'	System	18 Aug 2020 04:02:38
User entered 'None (1)'	System	18 Aug 2020 04:02:38

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-17T23:02:15', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c47f22c3-f4ca-471f-8aab-d43587601914'	System	18 Aug 2020 04:02:38
User entered 'No (N)'	System	18 Aug 2020 04:02:38

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-17T23:02:24', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c47f22c3-f4ca-471f-8aab-d43587601914'	System	18 Aug 2020 04:02:38
User entered 'No (N)'	System	18 Aug 2020 04:02:38

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-17T23:02:33', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c47f22c3-f4ca-471f-8aab-d43587601914'	System	18 Aug 2020 04:02:38
User entered 'None (1)'	System	18 Aug 2020 04:02:38

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-17T23:02:37', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c47f22c3-f4ca-471f-8aab-d43587601914'	System	18 Aug 2020 04:02:38
User entered '17 Aug 2020 23:02'	System	18 Aug 2020 04:02:38

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 6'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-18T21:21:37', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '50bce321-8579-4e5d-a949-c639818966f8'	System	19 Aug 2020 02:21:50
User entered 'None (1)'	System	19 Aug 2020 02:21:50

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-18T21:21:40', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '50bce321-8579-4e5d-a949-c639818966f8'	System	19 Aug 2020 02:21:50
User entered 'No (N)'	System	19 Aug 2020 02:21:50

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-18T21:21:42', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '50bce321-8579-4e5d-a949-c639818966f8'	System	19 Aug 2020 02:21:50
User entered 'No (N)'	System	19 Aug 2020 02:21:50

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-18T21:21:47', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '50bce321-8579-4e5d-a949-c639818966f8'	System	19 Aug 2020 02:21:50
User entered 'None (1)'	System	19 Aug 2020 02:21:50

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-18T21:21:49', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '50bce321-8579-4e5d-a949-c639818966f8'	System	19 Aug 2020 02:21:50
User entered '18 Aug 2020 21:21'	System	19 Aug 2020 02:21:50

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 7'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-20T11:47:12', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '41beee2c-12cc-4bf3-aebb-963e071d31d0'	System	20 Aug 2020 16:47:27
User entered 'None (1)'	System	20 Aug 2020 16:47:27

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-20T11:47:14', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '41beee2c-12cc-4bf3-aebb-963e071d31d0'	System	20 Aug 2020 16:47:27
User entered 'No (N)'	System	20 Aug 2020 16:47:27

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-20T11:47:16', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '41beee2c-12cc-4bf3-aebb-963e071d31d0'	System	20 Aug 2020 16:47:27
User entered 'No (N)'	System	20 Aug 2020 16:47:27

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-20T11:47:21', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '41beee2c-12cc-4bf3-aebb-963e071d31d0'	System	20 Aug 2020 16:47:27
User entered 'None (1)'	System	20 Aug 2020 16:47:27

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-20T11:47:24', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '41beee2c-12cc-4bf3-aebb-963e071d31d0'	System	20 Aug 2020 16:47:27
User entered '20 Aug 2020 11:47'	System	20 Aug 2020 16:47:27

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T13:06:30', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '91f0cc35-2c30-49f7-93dc-b198f2ac5ffb'	System	13 Aug 2020 18:06:57
User entered 'None (0)'	System	13 Aug 2020 18:06:57

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T13:06:32', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '91f0cc35-2c30-49f7-93dc-b198f2ac5ffb'	System	13 Aug 2020 18:06:57
User entered 'None (0)'	System	13 Aug 2020 18:06:57

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T13:06:35', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '91f0cc35-2c30-49f7-93dc-b198f2ac5ffb'	System	13 Aug 2020 18:06:57
User entered 'None (0)'	System	13 Aug 2020 18:06:57

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T13:06:40', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '91f0cc35-2c30-49f7-93dc-b198f2ac5ffb'	System	13 Aug 2020 18:06:57
User entered 'None (0)'	System	13 Aug 2020 18:06:57

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T13:06:43', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '91f0cc35-2c30-49f7-93dc-b198f2ac5ffb'	System	13 Aug 2020 18:06:57
User entered 'None (0)'	System	13 Aug 2020 18:06:57

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T13:06:45', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '91f0cc35-2c30-49f7-93dc-b198f2ac5ffb'	System	13 Aug 2020 18:06:57
User entered 'None (0)'	System	13 Aug 2020 18:06:57

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T13:06:50', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '91f0cc35-2c30-49f7-93dc-b198f2ac5ffb'	System	13 Aug 2020 18:06:57
User entered 'No (N)'	System	13 Aug 2020 18:06:57

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T13:06:55', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '91f0cc35-2c30-49f7-93dc-b198f2ac5ffb'	System	13 Aug 2020 18:06:57
User entered '13 Aug 2020 13:06'	System	13 Aug 2020 18:06:57

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '13 Aug 2020 12:49'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '13 Aug 2020 15:19'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T21:04:10', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '9fc378cd-d1ea-46f1-963a-9f200c45cc92'	System	14 Aug 2020 02:04:39
User entered 'None (0)'	System	14 Aug 2020 02:04:39

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T21:04:18', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '9fc378cd-d1ea-46f1-963a-9f200c45cc92'	System	14 Aug 2020 02:04:39
User entered 'None (0)'	System	14 Aug 2020 02:04:39

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T21:04:21', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '9fc378cd-d1ea-46f1-963a-9f200c45cc92'	System	14 Aug 2020 02:04:39
User entered 'None (0)'	System	14 Aug 2020 02:04:39

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T21:04:24', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '9fc378cd-d1ea-46f1-963a-9f200c45cc92'	System	14 Aug 2020 02:04:39
User entered 'None (0)'	System	14 Aug 2020 02:04:39

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T21:04:26', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '9fc378cd-d1ea-46f1-963a-9f200c45cc92'	System	14 Aug 2020 02:04:39
User entered 'None (0)'	System	14 Aug 2020 02:04:39

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T21:04:28', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '9fc378cd-d1ea-46f1-963a-9f200c45cc92'	System	14 Aug 2020 02:04:39
User entered 'None (0)'	System	14 Aug 2020 02:04:39

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T21:04:34', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '9fc378cd-d1ea-46f1-963a-9f200c45cc92'	System	14 Aug 2020 02:04:39
User entered 'No (N)'	System	14 Aug 2020 02:04:39

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-13T21:04:37', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '9fc378cd-d1ea-46f1-963a-9f200c45cc92'	System	14 Aug 2020 02:04:39
User entered '13 Aug 2020 21:04'	System	14 Aug 2020 02:04:39

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '13 Aug 2020 16:14'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 2'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-14T22:25:19', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'a2044096-a8d5-40f6-90c7-09e789586bfa'	System	15 Aug 2020 03:25:48
User entered 'None (0)'	System	15 Aug 2020 03:25:48

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-14T22:25:22', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'a2044096-a8d5-40f6-90c7-09e789586bfa'	System	15 Aug 2020 03:25:48
User entered 'None (0)'	System	15 Aug 2020 03:25:48

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-14T22:25:24', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'a2044096-a8d5-40f6-90c7-09e789586bfa'	System	15 Aug 2020 03:25:48
User entered 'None (0)'	System	15 Aug 2020 03:25:48

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-14T22:25:27', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'a2044096-a8d5-40f6-90c7-09e789586bfa'	System	15 Aug 2020 03:25:48
User entered 'None (0)'	System	15 Aug 2020 03:25:48

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-14T22:25:29', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'a2044096-a8d5-40f6-90c7-09e789586bfa'	System	15 Aug 2020 03:25:48
User entered 'None (0)'	System	15 Aug 2020 03:25:48

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-14T22:25:32', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'a2044096-a8d5-40f6-90c7-09e789586bfa'	System	15 Aug 2020 03:25:48
User entered 'None (0)'	System	15 Aug 2020 03:25:48

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-14T22:25:39', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'a2044096-a8d5-40f6-90c7-09e789586bfa'	System	15 Aug 2020 03:25:48
User entered 'No (N)'	System	15 Aug 2020 03:25:48

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-14T22:25:43', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'a2044096-a8d5-40f6-90c7-09e789586bfa'	System	15 Aug 2020 03:25:48
User entered '14 Aug 2020 22:25'	System	15 Aug 2020 03:25:48

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 3'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T00:23:20', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '76ab9ad1-7f21-4832-b9a8-c24315bf1f31'	System	16 Aug 2020 05:23:42
User entered 'None (0)'	System	16 Aug 2020 05:23:42

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T00:23:22', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '76ab9ad1-7f21-4832-b9a8-c24315bf1f31'	System	16 Aug 2020 05:23:42
User entered 'None (0)'	System	16 Aug 2020 05:23:42

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T00:23:24', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '76ab9ad1-7f21-4832-b9a8-c24315bf1f31'	System	16 Aug 2020 05:23:42
User entered 'None (0)'	System	16 Aug 2020 05:23:42

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T00:23:27', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '76ab9ad1-7f21-4832-b9a8-c24315bf1f31'	System	16 Aug 2020 05:23:42
User entered 'None (0)'	System	16 Aug 2020 05:23:42

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T00:23:29', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '76ab9ad1-7f21-4832-b9a8-c24315bf1f31'	System	16 Aug 2020 05:23:42
User entered 'None (0)'	System	16 Aug 2020 05:23:42

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T00:23:32', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '76ab9ad1-7f21-4832-b9a8-c24315bf1f31'	System	16 Aug 2020 05:23:42
User entered 'None (0)'	System	16 Aug 2020 05:23:42

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T00:23:36', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '76ab9ad1-7f21-4832-b9a8-c24315bf1f31'	System	16 Aug 2020 05:23:42
User entered 'No (N)'	System	16 Aug 2020 05:23:42

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T00:23:40', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '76ab9ad1-7f21-4832-b9a8-c24315bf1f31'	System	16 Aug 2020 05:23:42
User entered '16 Aug 2020 00:23'	System	16 Aug 2020 05:23:42

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 4'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T21:37:38', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd438bb85-b020-42b2-b128-bad7f7d8eec9'	System	17 Aug 2020 02:38:00
User entered 'None (0)'	System	17 Aug 2020 02:38:00

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T21:37:40', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd438bb85-b020-42b2-b128-bad7f7d8eec9'	System	17 Aug 2020 02:38:00
User entered 'None (0)'	System	17 Aug 2020 02:38:00

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T21:37:42', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd438bb85-b020-42b2-b128-bad7f7d8eec9'	System	17 Aug 2020 02:38:00
User entered 'None (0)'	System	17 Aug 2020 02:38:00

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T21:37:44', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd438bb85-b020-42b2-b128-bad7f7d8eec9'	System	17 Aug 2020 02:38:00
User entered 'None (0)'	System	17 Aug 2020 02:38:00

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T21:37:47', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd438bb85-b020-42b2-b128-bad7f7d8eec9'	System	17 Aug 2020 02:38:00
User entered 'None (0)'	System	17 Aug 2020 02:38:00

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T21:37:49', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd438bb85-b020-42b2-b128-bad7f7d8eec9'	System	17 Aug 2020 02:38:00
User entered 'None (0)'	System	17 Aug 2020 02:38:00

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T21:37:53', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd438bb85-b020-42b2-b128-bad7f7d8eec9'	System	17 Aug 2020 02:38:00
User entered 'No (N)'	System	17 Aug 2020 02:38:00

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-16T21:37:55', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd438bb85-b020-42b2-b128-bad7f7d8eec9'	System	17 Aug 2020 02:38:00
User entered '16 Aug 2020 21:37'	System	17 Aug 2020 02:38:00

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 5'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-17T23:02:44', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5798d9ff-4315-45cd-881c-710dfaceea8ac'	System	18 Aug 2020 04:03:09
User entered 'None (0)'	System	18 Aug 2020 04:03:09

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-17T23:02:46', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5798d9ff-4315-45cd-881c-710dfaeaa8ac'	System	18 Aug 2020 04:03:09
User entered 'None (0)'	System	18 Aug 2020 04:03:09

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-17T23:02:48', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5798d9ff-4315-45cd-881c-710dfaeaa8ac'	System	18 Aug 2020 04:03:09
User entered 'None (0)'	System	18 Aug 2020 04:03:09

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-17T23:02:50', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5798d9ff-4315-45cd-881c-710dfaeaa8ac'	System	18 Aug 2020 04:03:09
User entered 'None (0)'	System	18 Aug 2020 04:03:09

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-17T23:02:53', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5798d9ff-4315-45cd-881c-710dfaeaa8ac'	System	18 Aug 2020 04:03:09
User entered 'None (0)'	System	18 Aug 2020 04:03:09

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-17T23:02:57', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5798d9ff-4315-45cd-881c-710dfaceea8ac'	System	18 Aug 2020 04:03:09
User entered 'None (0)'	System	18 Aug 2020 04:03:09

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-17T23:03:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5798d9ff-4315-45cd-881c-710dfaceea8ac'	System	18 Aug 2020 04:03:09
User entered 'No (N)'	System	18 Aug 2020 04:03:09

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-17T23:03:05', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5798d9ff-4315-45cd-881c-710dfaceea8ac'	System	18 Aug 2020 04:03:09
User entered '17 Aug 2020 23:03'	System	18 Aug 2020 04:03:09

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 6'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-18T21:21:53', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5d3d0d62-abdd-49e3-a1f3-ed5411069b78'	System	19 Aug 2020 02:22:14
User entered 'None (0)'	System	19 Aug 2020 02:22:14

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-18T21:21:56', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5d3d0d62-abdd-49e3-a1f3-ed5411069b78'	System	19 Aug 2020 02:22:14
User entered 'None (0)'	System	19 Aug 2020 02:22:14

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-18T21:21:58', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5d3d0d62-abdd-49e3-a1f3-ed5411069b78'	System	19 Aug 2020 02:22:14
User entered 'None (0)'	System	19 Aug 2020 02:22:14

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-18T21:22:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5d3d0d62-abdd-49e3-a1f3-ed5411069b78'	System	19 Aug 2020 02:22:14
User entered 'None (0)'	System	19 Aug 2020 02:22:14

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-18T21:22:03', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5d3d0d62-abdd-49e3-a1f3-ed5411069b78'	System	19 Aug 2020 02:22:14
User entered 'None (0)'	System	19 Aug 2020 02:22:14

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-18T21:22:05', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5d3d0d62-abdd-49e3-a1f3-ed5411069b78'	System	19 Aug 2020 02:22:14
User entered 'None (0)'	System	19 Aug 2020 02:22:14

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-18T21:22:08', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5d3d0d62-abdd-49e3-a1f3-ed5411069b78'	System	19 Aug 2020 02:22:14
User entered 'No (N)'	System	19 Aug 2020 02:22:14

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-18T21:22:11', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '5d3d0d62-abdd-49e3-a1f3-ed5411069b78'	System	19 Aug 2020 02:22:14
User entered '18 Aug 2020 21:22'	System	19 Aug 2020 02:22:14

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 7'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-20T11:47:28', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '12362c0d-7873-4bd1-8bc2-b45c10910a25'	System	20 Aug 2020 16:47:46
User entered 'None (0)'	System	20 Aug 2020 16:47:46

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-20T11:47:30', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '12362c0d-7873-4bd1-8bc2-b45c10910a25'	System	20 Aug 2020 16:47:46
User entered 'None (0)'	System	20 Aug 2020 16:47:46

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-20T11:47:31', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '12362c0d-7873-4bd1-8bc2-b45c10910a25'	System	20 Aug 2020 16:47:46
User entered 'None (0)'	System	20 Aug 2020 16:47:46

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-20T11:47:33', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '12362c0d-7873-4bd1-8bc2-b45c10910a25'	System	20 Aug 2020 16:47:46
User entered 'None (0)'	System	20 Aug 2020 16:47:46

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-20T11:47:36', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '12362c0d-7873-4bd1-8bc2-b45c10910a25'	System	20 Aug 2020 16:47:46
User entered 'None (0)'	System	20 Aug 2020 16:47:46

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-20T11:47:38', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '12362c0d-7873-4bd1-8bc2-b45c10910a25'	System	20 Aug 2020 16:47:46
User entered 'None (0)'	System	20 Aug 2020 16:47:46

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-20T11:47:40', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '12362c0d-7873-4bd1-8bc2-b45c10910a25'	System	20 Aug 2020 16:47:46
User entered 'No (N)'	System	20 Aug 2020 16:47:46

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-08-20T11:47:43', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '12362c0d-7873-4bd1-8bc2-b45c10910a25'	System	20 Aug 2020 16:47:46
User entered '20 Aug 2020 11:47'	System	20 Aug 2020 16:47:46

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 18:02:07

US3862007

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	20 Aug 2020 22:58:30

US3862007

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '20 Aug 2020'	Coni Cheesman (b) (4)	20 Aug 2020 22:58:30

US3862007

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Contact Made (CONTACT MADE)'	Coni Cheesman (b) (4)	20 Aug 2020 22:58:30

US3862007

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Coni Cheesman (b) (4)	20 Aug 2020 22:58:30

US3862007

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	27 Aug 2020 22:52:14

US3862007

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'I'	System	27 Aug 2020 22:52:14

US3862007

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	27 Aug 2020 22:52:58

US3862007

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '27 Aug 2020'	Coni Cheesman (b) (4)	27 Aug 2020 22:52:58

US3862007

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Contact Made (CONTACT MADE)'	Coni Cheesman (b) (4)	27 Aug 2020 22:52:58

US3862007

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Coni Cheesman (b) (4)	27 Aug 2020 22:52:58

US3862007

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	03 Sep 2020 23:48:57

US3862007

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered '1'	System	03 Sep 2020 23:48:57

US3862007

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	03 Sep 2020 23:49:19

US3862007

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '3 Sep 2020'	Coni Cheesman (b) (4)	03 Sep 2020 23:49:19

US3862007

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Contact Made (CONTACT MADE)'	Coni Cheesman (b) (4)	03 Sep 2020 23:49:19

US3862007

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Coni Cheesman (b) (4)	03 Sep 2020 23:49:19

US3862007

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:20:54

US3862007

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered '1'	System	10 Sep 2020 21:20:54

US3862007

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:21:01

US3862007

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '10 Sep 2020'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:21:01

US3862007

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:21:01

US3862007

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'VISIT2'	System	10 Sep 2020 21:21:01

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User accepted default value 'Pre-Dose (PREDOSE)'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:22:34

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:22:34

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '10 Sep 2020'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:22:34

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '15:51'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:22:34

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered '10 Sep 2020 15:51'	System	10 Sep 2020 21:22:34

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Sep 2020 22:53:17
User entered '98.4' F reason for change: Data Entry Error	Sandra Francisco (b) (4)	10 Sep 2020 22:53:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Sep 2020 21:22:34
User entered '98' (non-conformant).	Carrie Kibler (b) (4)	10 Sep 2020 21:22:34

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Oral (Oral)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	10 Sep 2020 22:53:17
User entered empty.	Carrie Kibler (b) (4)	10 Sep 2020 21:22:34

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:22:34

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 22:53:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		10 Sep 2020 22:53:17
User entered '66' reason for change: Data Entry Error	Sandra Francisco (b) (4)	10 Sep 2020 22:53:17
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 21:22:34
User entered empty.	Carrie Kibler (b) (4)	10 Sep 2020 21:22:34

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'bpm'	System	10 Sep 2020 22:53:17
User entered empty.	System	10 Sep 2020 21:22:34

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 22:53:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		10 Sep 2020 22:53:17
User entered '18' reason for change: Data Entry Error	Sandra Francisco (b) (4)	10 Sep 2020 22:53:17
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 21:22:34
User entered empty.	Carrie Kibler (b) (4)	10 Sep 2020 21:22:34

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'breaths/min'	System	10 Sep 2020 22:53:17
User entered empty.	System	10 Sep 2020 21:22:34

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 22:53:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		10 Sep 2020 22:53:17
User entered '141' reason for change: Data Entry Error	Sandra Francisco (b) (4)	10 Sep 2020 22:53:17
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 21:22:34
User entered empty.	Carrie Kibler (b) (4)	10 Sep 2020 21:22:34

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'mmHg'	System	10 Sep 2020 22:53:17
User entered empty.	System	10 Sep 2020 21:22:34

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 22:53:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		10 Sep 2020 22:53:17
User entered '79' reason for change: Data Entry Error	Sandra Francisco (b) (4)	10 Sep 2020 22:53:17
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 21:22:34
User entered empty.	Carrie Kibler (b) (4)	10 Sep 2020 21:22:34

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'mmHg'	System	10 Sep 2020 22:53:17
User entered empty.	System	10 Sep 2020 21:22:34

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User accepted default value 'Post-Dose (POSTDOSE)'	Sandra Francisco (b) (4) (b) (4)	10 Sep 2020 22:02:50

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:53:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 22:53:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	10 Sep 2020 22:53:17
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 22:02:50
User entered empty.	Sandra Francisco (b) (4)	10 Sep 2020 22:02:50

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '10 Sep 2020' reason for change: Data Entry Error	Sandra Francisco (b) (4)	10 Sep 2020 22:53:17
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	10 Sep 2020 22:02:50
	(b) (4)	

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '17:26' reason for change: Data Entry Error	Sandra Francisco (b) (4)	10 Sep 2020 22:53:17
User entered empty.	Sandra Francisco (b) (4)	10 Sep 2020 22:02:50

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered '10 Sep 2020 17:26'	System	10 Sep 2020 22:53:17
User entered empty.	System	10 Sep 2020 22:02:50

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '98.8' F reason for change: Data Entry Error	Sandra Francisco (b) (4)	10 Sep 2020 22:53:17
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	10 Sep 2020 22:02:50
	(b) (4)	

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Oral (Oral)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	10 Sep 2020 22:53:17
User entered empty.	Sandra Francisco (b) (4)	10 Sep 2020 22:02:50

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Sandra Francisco (b) (4) (b) (4)	10 Sep 2020 22:02:50

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '65' reason for change: Data Entry Error	Sandra Francisco (b) (4)	10 Sep 2020 22:53:17
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	10 Sep 2020 22:02:50
	(b) (4)	

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'bpm'	System	10 Sep 2020 22:53:17
User entered empty.	System	10 Sep 2020 22:02:50

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '16' reason for change: Data Entry Error	Sandra Francisco (b) (4)	10 Sep 2020 22:53:17
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	10 Sep 2020 22:02:50
	(b) (4)	

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'breaths/min'	System	10 Sep 2020 22:53:17
User entered empty.	System	10 Sep 2020 22:02:50

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '140' reason for change: Data Entry Error	Sandra Francisco (b) (4)	10 Sep 2020 22:53:17
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	10 Sep 2020 22:02:50
	(b) (4)	

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'mmHg'	System	10 Sep 2020 22:53:17
User entered empty.	System	10 Sep 2020 22:02:50

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '81' reason for change: Data Entry Error	Sandra Francisco (b) (4)	10 Sep 2020 22:53:17
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	10 Sep 2020 22:02:50
	(b) (4)	

US3862007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'mmHg'	System	10 Sep 2020 22:53:17
User entered empty.	System	10 Sep 2020 22:02:50

US3862007

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:21:14

US3862007

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '10 Sep 2020'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:21:14

US3862007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	10 Sep 2020 21:53:41

US3862007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Sandra Francisco (b) (4) (b) (4)	10 Sep 2020 21:53:41

US3862007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Sandra Francisco (b) (4) (b) (4)	10 Sep 2020 21:53:41

US3862007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 21:53:41

US3862007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '10 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	10 Sep 2020 21:53:41

US3862007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '16:48'	Sandra Francisco (b) (4) (b) (4)	10 Sep 2020 21:53:41

US3862007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered '10 Sep 2020 16:48'	System	10 Sep 2020 21:53:41

US3862007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Left Arm (LEFT ARM)'	Sandra Francisco (b) (4) (b) (4)	10 Sep 2020 21:53:41

US3862007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'ONCE'	System	10 Sep 2020 21:53:41

US3862007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:10

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 21:53:41

US3862007

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:22:18

US3862007

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '10 Sep 2020'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:22:18

US3862007

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '16:08'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:22:18

US3862007

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered '10 Sep 2020 16:08'	System	10 Sep 2020 21:22:18

US3862007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:06:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '10 Sep 2020'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:21:57

US3862007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:06:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:21:57

US3862007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:21:57

US3862007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:06:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:21:57

US3862007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:06:10

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered empty.	System	10 Sep 2020 21:21:57

US3862007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:06:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:21:57

US3862007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:21:57

US3862007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:06:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '16:00'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:21:57

US3862007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:06:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered '10 Sep 2020 16:00'	System	10 Sep 2020 21:21:57

US3862007

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	10 Sep 2020 21:21:06

US3862007

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered '1'	System	10 Sep 2020 21:21:06

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-10T17:29:10', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c18ce4bc-bf65-49f5-a07b-c83c60d1a0f7'	System	10 Sep 2020 22:29:43
User entered 'Yes (Y)'	System	10 Sep 2020 22:29:43

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-10T17:29:30', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c18ce4bc-bf65-49f5-a07b-c83c60d1a0f7'	System	10 Sep 2020 22:29:43
User entered '98.8'	System	10 Sep 2020 22:29:43

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-10T17:29:34', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c18ce4bc-bf65-49f5-a07b-c83c60d1a0f7'	System	10 Sep 2020 22:29:43
User entered 'No (N)'	System	10 Sep 2020 22:29:43

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-10T17:29:39', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c18ce4bc-bf65-49f5-a07b-c83c60d1a0f7'	System	10 Sep 2020 22:29:43
User entered '10 Sep 2020 17:29'	System	10 Sep 2020 22:29:43

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '10 Sep 2020 17:08'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '10 Sep 2020 19:38'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '10 Sep 2020 20:33'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 2'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:18:09', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '601dfcb2-71ab-4926-afc6-de3a0ce8f8d4'	System	11 Sep 2020 22:18:31
User entered 'Yes (Y)'	System	11 Sep 2020 22:18:31

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:18:15', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '601dfcb2-71ab-4926-afc6-de3a0ce8f8d4'	System	11 Sep 2020 22:18:31
User entered '100.8'	System	11 Sep 2020 22:18:31

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:18:19', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '601dfcb2-71ab-4926-afc6-de3a0ce8f8d4'	System	11 Sep 2020 22:18:31
User entered 'No (N)'	System	11 Sep 2020 22:18:31

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:18:23', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '601dfcb2-71ab-4926-afc6-de3a0ce8f8d4'	System	11 Sep 2020 22:18:31
User entered '11 Sep 2020 17:18'	System	11 Sep 2020 22:18:31

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 3'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:33:03', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '4bc3e4eb-9bfc-44a8-9691-8fd2b82184b6'	System	12 Sep 2020 23:33:27
User entered 'Yes (Y)'	System	12 Sep 2020 23:33:27

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:33:09', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '4bc3e4eb-9bfc-44a8-9691-8fd2b82184b6'	System	12 Sep 2020 23:33:27
User entered '98.1'	System	12 Sep 2020 23:33:27

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:33:13', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '4bc3e4eb-9bfc-44a8-9691-8fd2b82184b6'	System	12 Sep 2020 23:33:27
User entered 'No (N)'	System	12 Sep 2020 23:33:27

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:33:24', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '4bc3e4eb-9bfc-44a8-9691-8fd2b82184b6'	System	12 Sep 2020 23:33:27
User entered '12 Sep 2020 18:33'	System	12 Sep 2020 23:33:27

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 4'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:48:44', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f74d28cc-6c89-4c33-93ca-fe2d822ef27c'	System	14 Sep 2020 03:48:55
User entered 'Yes (Y)'	System	14 Sep 2020 03:48:55

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:48:48', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f74d28cc-6c89-4c33-93ca-fe2d822ef27c'	System	14 Sep 2020 03:48:55
User entered '98.5'	System	14 Sep 2020 03:48:55

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:48:52', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f74d28cc-6c89-4c33-93ca-fe2d822ef27c'	System	14 Sep 2020 03:48:55
User entered 'No (N)'	System	14 Sep 2020 03:48:55

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:48:56', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f74d28cc-6c89-4c33-93ca-fe2d822ef27c'	System	14 Sep 2020 03:48:55
User entered '13 Sep 2020 22:48'	System	14 Sep 2020 03:48:55

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 5'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:21:23', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'bd0d2949-6c93-4781-a4c8-3ab299ab2459'	System	15 Sep 2020 00:21:41
User entered 'Yes (Y)'	System	15 Sep 2020 00:21:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:21:29', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'bd0d2949-6c93-4781-a4c8-3ab299ab2459'	System	15 Sep 2020 00:21:41
User entered '98.5'	System	15 Sep 2020 00:21:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:21:33', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'bd0d2949-6c93-4781-a4c8-3ab299ab2459'	System	15 Sep 2020 00:21:41
User entered 'No (N)'	System	15 Sep 2020 00:21:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:21:39', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'bd0d2949-6c93-4781-a4c8-3ab299ab2459'	System	15 Sep 2020 00:21:41
User entered '14 Sep 2020 19:21'	System	15 Sep 2020 00:21:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 6'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 7'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-17T11:13:35', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c60131bc-86a8-4398-9d75-61c1d5f9b2aa'	System	17 Sep 2020 16:13:47
User entered 'No (N)'	System	17 Sep 2020 16:13:47

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-17T11:13:38', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c60131bc-86a8-4398-9d75-61c1d5f9b2aa'	System	17 Sep 2020 16:13:47
User entered 'No (N)'	System	17 Sep 2020 16:13:47

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-17T11:13:43', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c60131bc-86a8-4398-9d75-61c1d5f9b2aa'	System	17 Sep 2020 16:13:47
User entered '17 Sep 2020 11:13'	System	17 Sep 2020 16:13:47

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-10T17:29:52', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '10c5bcea-d857-4a49-8274-dfb4d1e9dd97'	System	10 Sep 2020 22:30:07
User entered 'None (1)'	System	10 Sep 2020 22:30:07

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-10T17:29:54', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '10c5bcea-d857-4a49-8274-dfb4d1e9dd97'	System	10 Sep 2020 22:30:07
User entered 'No (N)'	System	10 Sep 2020 22:30:07

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-10T17:29:57', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '10c5bcea-d857-4a49-8274-dfb4d1e9dd97'	System	10 Sep 2020 22:30:07
User entered 'No (N)'	System	10 Sep 2020 22:30:07

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-10T17:30:01', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '10c5bcea-d857-4a49-8274-dfb4d1e9dd97'	System	10 Sep 2020 22:30:07
User entered 'None (1)'	System	10 Sep 2020 22:30:07

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-10T17:30:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '10c5bcea-d857-4a49-8274-dfb4d1e9dd97'	System	10 Sep 2020 22:30:07
User entered '10 Sep 2020 17:30'	System	10 Sep 2020 22:30:07

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '10 Sep 2020 17:08'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '10 Sep 2020 19:38'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '10 Sep 2020 20:33'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 2'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:18:31', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '34cd287c-15cd-40cf-bad3-279a5259092c'	System	11 Sep 2020 22:21:53
User entered 'None (1)'	System	11 Sep 2020 22:21:53

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:18:35', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '34cd287c-15cd-40cf-bad3-279a5259092c'	System	11 Sep 2020 22:21:53
User entered 'No (N)'	System	11 Sep 2020 22:21:53

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:21:21', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '34cd287c-15cd-40cf-bad3-279a5259092c'	System	11 Sep 2020 22:21:53
User entered 'Yes (Y)'	System	11 Sep 2020 22:21:53

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:21:37', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '34cd287c-15cd-40cf-bad3-279a5259092c'	System	11 Sep 2020 22:21:53
User entered '2'	System	11 Sep 2020 22:21:53

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:21:47', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '34cd287c-15cd-40cf-bad3-279a5259092c'	System	11 Sep 2020 22:21:53
User entered 'None (1)'	System	11 Sep 2020 22:21:53

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:21:53', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '34cd287c-15cd-40cf-bad3-279a5259092c'	System	11 Sep 2020 22:21:53
User entered '11 Sep 2020 17:21'	System	11 Sep 2020 22:21:53

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 3'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:33:36', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '0a076fe8-e6fa-4c1b-b28b-2cf695d04afd'	System	12 Sep 2020 23:35:19
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 23:35:19

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:33:39', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '0a076fe8-e6fa-4c1b-b28b-2cf695d04afd'	System	12 Sep 2020 23:35:19
User entered 'Yes (Y)'	System	12 Sep 2020 23:35:19

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:34:42', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '0a076fe8-e6fa-4c1b-b28b-2cf695d04afd' User entered '50'	System	12 Sep 2020 23:35:19
	System	12 Sep 2020 23:35:19

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:34:56', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '0a076fe8-e6fa-4c1b-b28b-2cf695d04afd'	System	12 Sep 2020 23:35:19
User entered 'Yes (Y)'	System	12 Sep 2020 23:35:19

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:35:01', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '0a076fe8-e6fa-4c1b-b28b-2cf695d04afd' User entered '2'	System	12 Sep 2020 23:35:19
	System	12 Sep 2020 23:35:19

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:35:11', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '0a076fe8-e6fa-4c1b-b28b-2cf695d04afd'	System	12 Sep 2020 23:35:19
User entered 'None (1)'	System	12 Sep 2020 23:35:19

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:35:19', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '0a076fe8-e6fa-4c1b-b28b-2cf695d04afd'	System	12 Sep 2020 23:35:19
User entered '12 Sep 2020 18:35'	System	12 Sep 2020 23:35:19

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 4'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:49:01', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '7a49573a-d2f9-4625-85d0-6a5236d397b0'	System	14 Sep 2020 03:49:39
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 03:49:39

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:49:11', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '7a49573a-d2f9-4625-85d0-6a5236d397b0'	System	14 Sep 2020 03:49:39
User entered 'No (N)'	System	14 Sep 2020 03:49:39

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:49:14', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '7a49573a-d2f9-4625-85d0-6a5236d397b0'	System	14 Sep 2020 03:49:39
User entered 'Yes (Y)'	System	14 Sep 2020 03:49:39

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:49:31', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '7a49573a-d2f9-4625-85d0-6a5236d397b0'	System	14 Sep 2020 03:49:39
User entered '10'	System	14 Sep 2020 03:49:39

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:49:34', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '7a49573a-d2f9-4625-85d0-6a5236d397b0'	System	14 Sep 2020 03:49:39
User entered 'None (1)'	System	14 Sep 2020 03:49:39

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:49:38', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '7a49573a-d2f9-4625-85d0-6a5236d397b0'	System	14 Sep 2020 03:49:39
User entered '13 Sep 2020 22:49'	System	14 Sep 2020 03:49:39

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 5'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:21:43', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'bef32f2d-4d67-4e7a-93b7-69e0aa08adc8'	System	15 Sep 2020 00:22:09
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 00:22:09

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:21:49', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'bef32f2d-4d67-4e7a-93b7-69e0aa08adc8'	System	15 Sep 2020 00:22:09
User entered 'No (N)'	System	15 Sep 2020 00:22:09

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:21:53', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'bef32f2d-4d67-4e7a-93b7-69e0aa08adc8'	System	15 Sep 2020 00:22:09
User entered 'Yes (Y)'	System	15 Sep 2020 00:22:09

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:22:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'bef32f2d-4d67-4e7a-93b7-69e0aa08adc8'	System	15 Sep 2020 00:22:09
User entered '2'	System	15 Sep 2020 00:22:09

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:22:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'bef32f2d-4d67-4e7a-93b7-69e0aa08adc8'	System	15 Sep 2020 00:22:09
User entered 'None (1)'	System	15 Sep 2020 00:22:09

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:22:07', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'bef32f2d-4d67-4e7a-93b7-69e0aa08adc8'	System	15 Sep 2020 00:22:09
User entered '14 Sep 2020 19:22'	System	15 Sep 2020 00:22:09

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 6'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 7'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-17T11:18:44', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'b6586c01-f68b-4e6d-84c6-d409e5c8c67f'	System	17 Sep 2020 16:19:08
User entered 'None (1)'	System	17 Sep 2020 16:19:08

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-17T11:18:46', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'b6586c01-f68b-4e6d-84c6-d409e5c8c67f'	System	17 Sep 2020 16:19:08
User entered 'No (N)'	System	17 Sep 2020 16:19:08

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-17T11:18:48', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'b6586c01-f68b-4e6d-84c6-d409e5c8c67f'	System	17 Sep 2020 16:19:08
User entered 'No (N)'	System	17 Sep 2020 16:19:08

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-17T11:19:01', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'b6586c01-f68b-4e6d-84c6-d409e5c8c67f'	System	17 Sep 2020 16:19:08
User entered 'None (1)'	System	17 Sep 2020 16:19:08

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-17T11:19:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'b6586c01-f68b-4e6d-84c6-d409e5c8c67f'	System	17 Sep 2020 16:19:08
User entered '17 Sep 2020 11:19'	System	17 Sep 2020 16:19:08

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-10T17:30:09', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'fc5df9e5-0b3b-437e-bbe9-9a57de38adb1'	System	10 Sep 2020 22:30:33
User entered 'None (0)'	System	10 Sep 2020 22:30:33

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-10T17:30:12', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'fc5df9e5-0b3b-437e-bbe9-9a57de38adb1'	System	10 Sep 2020 22:30:33
User entered 'None (0)'	System	10 Sep 2020 22:30:33

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-10T17:30:14', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'fc5df9e5-0b3b-437e-bbe9-9a57de38adb1'	System	10 Sep 2020 22:30:33
User entered 'None (0)'	System	10 Sep 2020 22:30:33

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-10T17:30:16', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'fc5df9e5-0b3b-437e-bbe9-9a57de38adb1'	System	10 Sep 2020 22:30:33
User entered 'None (0)'	System	10 Sep 2020 22:30:33

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-10T17:30:18', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'fc5df9e5-0b3b-437e-bbe9-9a57de38adb1'	System	10 Sep 2020 22:30:33
User entered 'None (0)'	System	10 Sep 2020 22:30:33

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-10T17:30:23', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'fc5df9e5-0b3b-437e-bbe9-9a57de38adb1'	System	10 Sep 2020 22:30:33
User entered 'None (0)'	System	10 Sep 2020 22:30:33

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-10T17:30:28', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'fc5df9e5-0b3b-437e-bbe9-9a57de38adb1'	System	10 Sep 2020 22:30:33
User entered 'No (N)'	System	10 Sep 2020 22:30:33

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-10T17:30:31', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'fc5df9e5-0b3b-437e-bbe9-9a57de38adb1'	System	10 Sep 2020 22:30:33
User entered '10 Sep 2020 17:30'	System	10 Sep 2020 22:30:33

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '10 Sep 2020 17:08'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '10 Sep 2020 19:38'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '10 Sep 2020 20:33'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 2'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:22:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '90dd32de-aa81-4128-b59b-d759b3709462'	System	11 Sep 2020 22:22:49
User entered 'None (0)'	System	11 Sep 2020 22:22:49

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:22:06', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '90dd32de-aa81-4128-b59b-d759b3709462'	System	11 Sep 2020 22:22:49
User entered 'No interference with activity (1)'	System	11 Sep 2020 22:22:49

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:22:16', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '90dd32de-aa81-4128-b59b-d759b3709462'	System	11 Sep 2020 22:22:49
User entered 'No interference with activity (1)'	System	11 Sep 2020 22:22:49

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:22:24', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '90dd32de-aa81-4128-b59b-d759b3709462'	System	11 Sep 2020 22:22:49
User entered 'No interference with activity (1)'	System	11 Sep 2020 22:22:49

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:22:27', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '90dd32de-aa81-4128-b59b-d759b3709462'	System	11 Sep 2020 22:22:49
User entered 'None (0)'	System	11 Sep 2020 22:22:49

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:22:31', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '90dd32de-aa81-4128-b59b-d759b3709462'	System	11 Sep 2020 22:22:49
User entered 'None (0)'	System	11 Sep 2020 22:22:49

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:22:34', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '90dd32de-aa81-4128-b59b-d759b3709462'	System	11 Sep 2020 22:22:49
User entered 'No (N)'	System	11 Sep 2020 22:22:49

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-11T17:22:41', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '90dd32de-aa81-4128-b59b-d759b3709462'	System	11 Sep 2020 22:22:49
User entered '11 Sep 2020 17:22'	System	11 Sep 2020 22:22:49

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 3'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:35:32', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '98aa7b13-5209-48c8-82eb-8041e075a3b8'	System	12 Sep 2020 23:36:14
User entered 'None (0)'	System	12 Sep 2020 23:36:14

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:35:37', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '98aa7b13-5209-48c8-82eb-8041e075a3b8'	System	12 Sep 2020 23:36:14
User entered 'None (0)'	System	12 Sep 2020 23:36:14

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:35:47', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '98aa7b13-5209-48c8-82eb-8041e075a3b8'	System	12 Sep 2020 23:36:14
User entered 'None (0)'	System	12 Sep 2020 23:36:14

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:35:57', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '98aa7b13-5209-48c8-82eb-8041e075a3b8'	System	12 Sep 2020 23:36:14
User entered 'None (0)'	System	12 Sep 2020 23:36:14

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:36:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '98aa7b13-5209-48c8-82eb-8041e075a3b8'	System	12 Sep 2020 23:36:14
User entered 'None (0)'	System	12 Sep 2020 23:36:14

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:36:03', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '98aa7b13-5209-48c8-82eb-8041e075a3b8'	System	12 Sep 2020 23:36:14
User entered 'None (0)'	System	12 Sep 2020 23:36:14

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:36:09', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '98aa7b13-5209-48c8-82eb-8041e075a3b8'	System	12 Sep 2020 23:36:14
User entered 'No (N)'	System	12 Sep 2020 23:36:14

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-12T18:36:13', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '98aa7b13-5209-48c8-82eb-8041e075a3b8'	System	12 Sep 2020 23:36:14
User entered '12 Sep 2020 18:36'	System	12 Sep 2020 23:36:14

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 4'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:49:42', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f31fc536-264e-40de-9dc2-07b0b2609d98'	System	14 Sep 2020 03:50:03
User entered 'None (0)'	System	14 Sep 2020 03:50:03

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:49:45', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f31fc536-264e-40de-9dc2-07b0b2609d98'	System	14 Sep 2020 03:50:03
User entered 'None (0)'	System	14 Sep 2020 03:50:03

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:49:47', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f31fc536-264e-40de-9dc2-07b0b2609d98'	System	14 Sep 2020 03:50:03
User entered 'None (0)'	System	14 Sep 2020 03:50:03

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:49:50', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f31fc536-264e-40de-9dc2-07b0b2609d98'	System	14 Sep 2020 03:50:03
User entered 'None (0)'	System	14 Sep 2020 03:50:03

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:49:55', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f31fc536-264e-40de-9dc2-07b0b2609d98'	System	14 Sep 2020 03:50:03
User entered 'None (0)'	System	14 Sep 2020 03:50:03

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:49:57', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f31fc536-264e-40de-9dc2-07b0b2609d98'	System	14 Sep 2020 03:50:03
User entered 'None (0)'	System	14 Sep 2020 03:50:03

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:50:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f31fc536-264e-40de-9dc2-07b0b2609d98'	System	14 Sep 2020 03:50:03
User entered 'No (N)'	System	14 Sep 2020 03:50:03

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-13T22:50:03', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f31fc536-264e-40de-9dc2-07b0b2609d98'	System	14 Sep 2020 03:50:03
User entered '13 Sep 2020 22:50'	System	14 Sep 2020 03:50:03

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 5'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:22:12', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'e04b19ac-133d-4377-89bd-6f3358e7bea4'	System	15 Sep 2020 00:22:54
User entered 'None (0)'	System	15 Sep 2020 00:22:54

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:22:19', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'e04b19ac-133d-4377-89bd-6f3358e7bea4'	System	15 Sep 2020 00:22:54
User entered 'No interference with activity (1)'	System	15 Sep 2020 00:22:54

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:22:29', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'e04b19ac-133d-4377-89bd-6f3358e7bea4'	System	15 Sep 2020 00:22:54
User entered 'None (0)'	System	15 Sep 2020 00:22:54

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:22:32', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'e04b19ac-133d-4377-89bd-6f3358e7bea4'	System	15 Sep 2020 00:22:54
User entered 'None (0)'	System	15 Sep 2020 00:22:54

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:22:35', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'e04b19ac-133d-4377-89bd-6f3358e7bea4'	System	15 Sep 2020 00:22:54
User entered 'None (0)'	System	15 Sep 2020 00:22:54

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:22:37', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'e04b19ac-133d-4377-89bd-6f3358e7bea4'	System	15 Sep 2020 00:22:54
User entered 'None (0)'	System	15 Sep 2020 00:22:54

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:22:39', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'e04b19ac-133d-4377-89bd-6f3358e7bea4'	System	15 Sep 2020 00:22:54
User entered 'No (N)'	System	15 Sep 2020 00:22:54

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-14T19:22:42', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'e04b19ac-133d-4377-89bd-6f3358e7bea4'	System	15 Sep 2020 00:22:54
User entered '14 Sep 2020 19:22'	System	15 Sep 2020 00:22:54

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 6'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	10 Sep 2020 21:53:41
User entered 'Day 7'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-17T11:19:09', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd0a6c3de-1c72-4554-8e65-d342cbae6dc8'	System	17 Sep 2020 16:19:27
User entered 'None (0)'	System	17 Sep 2020 16:19:27

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-17T11:19:11', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd0a6c3de-1c72-4554-8e65-d342cbae6dc8'	System	17 Sep 2020 16:19:27
User entered 'None (0)'	System	17 Sep 2020 16:19:27

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-17T11:19:13', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd0a6c3de-1c72-4554-8e65-d342cbae6dc8'	System	17 Sep 2020 16:19:27
User entered 'None (0)'	System	17 Sep 2020 16:19:27

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-17T11:19:14', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd0a6c3de-1c72-4554-8e65-d342cbae6dc8'	System	17 Sep 2020 16:19:27
User entered 'None (0)'	System	17 Sep 2020 16:19:27

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-17T11:19:16', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd0a6c3de-1c72-4554-8e65-d342cbae6dc8'	System	17 Sep 2020 16:19:27
User entered 'None (0)'	System	17 Sep 2020 16:19:27

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-17T11:19:19', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd0a6c3de-1c72-4554-8e65-d342cbae6dc8'	System	17 Sep 2020 16:19:27
User entered 'None (0)'	System	17 Sep 2020 16:19:27

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-17T11:19:21', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd0a6c3de-1c72-4554-8e65-d342cbae6dc8'	System	17 Sep 2020 16:19:27
User entered 'No (N)'	System	17 Sep 2020 16:19:27

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-09-17T11:19:24', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd0a6c3de-1c72-4554-8e65-d342cbae6dc8'	System	17 Sep 2020 16:19:27
User entered '17 Sep 2020 11:19'	System	17 Sep 2020 16:19:27

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 21:53:41

US3862007

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 21:53:41

US3862007

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	18 Sep 2020 23:08:48

US3862007

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '17 Sep 2020'	Coni Cheesman (b) (4)	18 Sep 2020 23:08:48

US3862007

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Contact Made (CONTACT MADE)'	Coni Cheesman (b) (4)	18 Sep 2020 23:08:48

US3862007

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Coni Cheesman (b) (4)	18 Sep 2020 23:08:48

US3862007

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	24 Sep 2020 23:36:16

US3862007

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered '1'	System	24 Sep 2020 23:36:16

US3862007

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	24 Sep 2020 23:45:07

US3862007

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '24 Sep 2020'	Chanei Henry (b) (4) (b) (4)	24 Sep 2020 23:45:07

US3862007

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Contact Made (CONTACT MADE)'	Chanei Henry (b) (4) (b) (4)	24 Sep 2020 23:45:07

US3862007

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Chanei Henry (b) (4) (b) (4)	24 Sep 2020 23:45:07

US3862007

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	25 Sep 2020 14:46:50

US3862007

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'I'	System	25 Sep 2020 14:46:50

US3862007

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	02 Oct 2020 00:03:31

US3862007

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '1 Oct 2020'	Coni Cheesman (b) (4)	02 Oct 2020 00:03:31

US3862007

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Contact Made (CONTACT MADE)'	Coni Cheesman (b) (4)	02 Oct 2020 00:03:31

US3862007

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Coni Cheesman (b) (4)	02 Oct 2020 00:03:31

US3862007

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:29:21

US3862007

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'I'	System	06 Oct 2020 20:29:21

US3862007

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:35:36

US3862007

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '6 Oct 2020'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:35:36

US3862007

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:35:36

US3862007

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User entered 'VISIT3'	System	06 Oct 2020 20:35:36

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:36:03

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '6 Oct 2020'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:36:03

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '15:55'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:36:03

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User entered '6 Oct 2020 15:55'	System	06 Oct 2020 20:36:03

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '97.7' F	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:36:03

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Other (Other)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:36:03

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'temporal'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:36:03

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '75'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:36:03

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User entered 'bpm'	System	06 Oct 2020 20:36:03

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '16'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:36:03

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User entered 'breaths/min'	System	06 Oct 2020 20:36:03

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '109'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:36:03

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User entered 'mmHg'	System	06 Oct 2020 20:36:03

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	06 Oct 2020 20:36:17
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	06 Oct 2020 20:36:17
User entered '60' reason for change: Data Entry Error	Carrie Kibler (b) (4)	06 Oct 2020 20:36:17
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	06 Oct 2020 20:36:03
User entered '59'	Carrie Kibler (b) (4)	06 Oct 2020 20:36:03

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51
User entered 'mmHg'	System	06 Oct 2020 20:36:03

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51

US3862007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:51

US3862007

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:37:03

US3862007

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:37:03

US3862007

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:37:13

US3862007

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '6 Oct 2020'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:37:13

US3862007

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered '15:34'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:37:13

US3862007

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered '6 Oct 2020 15:34'	System	06 Oct 2020 20:37:13

US3862007

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:30:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:37:18

US3862007

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered '1'	System	06 Oct 2020 20:37:18

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 64'	System	13 Aug 2020 18:02:07

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05
Data entry locked.	System	13 Aug 2020 18:02:07
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 18:02:07

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05
Data entry locked.	System	13 Aug 2020 18:02:07
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 71'	System	13 Aug 2020 18:02:07

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05
Data entry locked.	System	13 Aug 2020 18:02:07
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 18:02:07

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05
Data entry locked.	System	13 Aug 2020 18:02:07
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 78'	System	13 Aug 2020 18:02:07

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05
Data entry locked.	System	13 Aug 2020 18:02:07
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 18:02:07

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05
Data entry locked.	System	13 Aug 2020 18:02:07
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 92'	System	13 Aug 2020 18:02:07

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:50:49', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered 'Yes (Y)'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:51:13', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered 'No (N)'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:54:28', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered 'Yes (Y)'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '0'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '0'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '0'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '0'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '0'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '0'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '1'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '0'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '0'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '0'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '0'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '0'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '0'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '0'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '0'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '0'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '0'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:11', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:18', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered 'Yes (Y)'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:29', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-11-10T06:55:40', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '8418bbd8-aacb-4c72-9fbf-f2ce03818f57'	System	10 Nov 2020 12:55:51
User entered '10 Nov 2020 06:55:40'	System	10 Nov 2020 12:55:51

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 18:02:07

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:48:29
Data entry locked.	System	13 Aug 2020 18:02:07
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05
Data entry locked.	System	13 Aug 2020 18:02:07
User entered 'Day 99'	System	13 Aug 2020 18:02:07

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05
Data entry locked.	System	13 Aug 2020 18:02:07
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 18:02:07

US3862007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:12:05
Data entry locked.	System	13 Aug 2020 18:02:07
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 18:02:07

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2020-12-12T01:14:42', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '900bff02-0dea-4caa-9430-1f4452c18b3b'	System	12 Dec 2020 07:14:56
User entered 'No (N)'	System	12 Dec 2020 07:14:56

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2020-12-12T01:14:49', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '900bff02-0dea-4caa-9430-1f4452c18b3b'	System	12 Dec 2020 07:14:56
User entered 'No (N)'	System	12 Dec 2020 07:14:56

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-12-12T01:14:55', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '900bff02-0dea-4caa-9430-1f4452c18b3b'	System	12 Dec 2020 07:14:56
User entered '12 Dec 2020 01:14:55'	System	12 Dec 2020 07:14:56

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2020-12-19T08:19:48', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd56fe7ed-635c-41ac-8694-1a06668244b5'	System	19 Dec 2020 14:20:03
User entered 'No (N)'	System	19 Dec 2020 14:20:03

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2020-12-19T08:19:56', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd56fe7ed-635c-41ac-8694-1a06668244b5'	System	19 Dec 2020 14:20:03
User entered 'No (N)'	System	19 Dec 2020 14:20:03

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-12-19T08:20:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd56fe7ed-635c-41ac-8694-1a06668244b5'	System	19 Dec 2020 14:20:03
User entered '19 Dec 2020 08:20:00'	System	19 Dec 2020 14:20:03

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2020-12-26T11:40:33', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '29d30f42-16e0-42f4-b7c1-31d350929e0a'	System	26 Dec 2020 17:42:19
User entered 'No (N)'	System	26 Dec 2020 17:42:19

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2020-12-26T11:42:05', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '29d30f42-16e0-42f4-b7c1-31d350929e0a'	System	26 Dec 2020 17:42:19
User entered 'No (N)'	System	26 Dec 2020 17:42:19

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2020-12-26T11:42:18', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '29d30f42-16e0-42f4-b7c1-31d350929e0a'	System	26 Dec 2020 17:42:19
User entered '26 Dec 2020 11:42:18'	System	26 Dec 2020 17:42:19

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-01-02T11:20:57', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '3f98017b-adaf-4ac0-8c0d-f99ad305df6d'	System	02 Jan 2021 17:21:12
User entered 'No (N)'	System	02 Jan 2021 17:21:12

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-01-02T11:21:05', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '3f98017b-adaf-4ac0-8c0d-f99ad305df6d'	System	02 Jan 2021 17:21:12
User entered 'No (N)'	System	02 Jan 2021 17:21:12

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-01-02T11:21:10', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '3f98017b-adaf-4ac0-8c0d-f99ad305df6d'	System	02 Jan 2021 17:21:12
User entered '02 Jan 2021 11:21:10'	System	02 Jan 2021 17:21:12

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-01-09T00:01:40', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '1f2b2e84-b75a-4026-999b-ace405cff6f4'	System	09 Jan 2021 06:02:39
User entered 'No (N)'	System	09 Jan 2021 06:02:39

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-01-09T00:01:45', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '1f2b2e84-b75a-4026-999b-ace405cff6f4'	System	09 Jan 2021 06:02:39
User entered 'No (N)'	System	09 Jan 2021 06:02:39

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-01-09T00:01:53', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '1f2b2e84-b75a-4026-999b-ace405cff6f4'	System	09 Jan 2021 06:02:39
User entered '09 Jan 2021 00:01:53'	System	09 Jan 2021 06:02:39

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-01-17T00:05:51', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd5d240b2-5abe-4908-975f-a2c656902a4c'	System	17 Jan 2021 06:06:03
User entered 'No (N)'	System	17 Jan 2021 06:06:03

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-01-17T00:05:54', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd5d240b2-5abe-4908-975f-a2c656902a4c'	System	17 Jan 2021 06:06:03
User entered 'No (N)'	System	17 Jan 2021 06:06:03

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-01-17T00:05:59', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd5d240b2-5abe-4908-975f-a2c656902a4c' User entered '17 Jan 2021 00:05:59'	System	17 Jan 2021 06:06:03
	System	17 Jan 2021 06:06:03

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-01-23T11:20:33', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f303fbf7-24d3-4778-84a4-0ef14991e008'	System	23 Jan 2021 17:20:48
User entered 'No (N)'	System	23 Jan 2021 17:20:48

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-01-23T11:20:40', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f303fbf7-24d3-4778-84a4-0ef14991e008'	System	23 Jan 2021 17:20:48
User entered 'No (N)'	System	23 Jan 2021 17:20:48

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-01-23T11:20:44', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f303fbf7-24d3-4778-84a4-0ef14991e008'	System	23 Jan 2021 17:20:48
User entered '23 Jan 2021 11:20:44'	System	23 Jan 2021 17:20:48

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-01-30T11:21:49', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'fca06463-d848-473d-a625-7a4436f6b4a8'	System	30 Jan 2021 16:21:59
User entered 'No (N)'	System	30 Jan 2021 16:21:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-01-30T11:21:53', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'fca06463-d848-473d-a625-7a4436f6b4a8'	System	30 Jan 2021 16:21:59
User entered 'No (N)'	System	30 Jan 2021 16:21:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-01-30T11:21:56', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'fca06463-d848-473d-a625-7a4436f6b4a8' User entered '30 Jan 2021 11:21:56'	System	30 Jan 2021 16:21:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-02-06T16:42:43', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f10ab1cd-5f6d-4ead-b9a8-edbe2f801871'	System	06 Feb 2021 21:42:55
User entered 'No (N)'	System	06 Feb 2021 21:42:55

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-02-06T16:42:48', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f10ab1cd-5f6d-4ead-b9a8-edbe2f801871'	System	06 Feb 2021 21:42:55
User entered 'No (N)'	System	06 Feb 2021 21:42:55

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-02-06T16:42:51', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'f10ab1cd-5f6d-4ead-b9a8-edbe2f801871'	System	06 Feb 2021 21:42:55
User entered '06 Feb 2021 16:42:51'	System	06 Feb 2021 21:42:55

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-02-13T10:57:52', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c3ab5b59-788f-4dc6-bb34-5fb2d52cdf84'	System	13 Feb 2021 15:58:07
User entered 'No (N)'	System	13 Feb 2021 15:58:07

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-02-13T10:57:58', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c3ab5b59-788f-4dc6-bb34-5fb2d52cdf84'	System	13 Feb 2021 15:58:07
User entered 'No (N)'	System	13 Feb 2021 15:58:07

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-02-13T10:58:01', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c3ab5b59-788f-4dc6-bb34-5fb2d52cdf84'	System	13 Feb 2021 15:58:07
User entered '13 Feb 2021 10:58:01'	System	13 Feb 2021 15:58:07

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-02-20T10:31:04', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c27bb602-606a-43b5-84d4-df7bd1d00dca'	System	20 Feb 2021 15:31:13
User entered 'No (N)'	System	20 Feb 2021 15:31:13

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-02-20T10:31:07', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c27bb602-606a-43b5-84d4-df7bd1d00dca'	System	20 Feb 2021 15:31:13
User entered 'No (N)'	System	20 Feb 2021 15:31:13

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-02-20T10:31:11', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'c27bb602-606a-43b5-84d4-df7bd1d00dca' User entered '20 Feb 2021 10:31:11'	System	20 Feb 2021 15:31:13
	System	20 Feb 2021 15:31:13

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-02-27T10:31:55-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd05f5636-fc55-40ec-8870-43dc63892491'	System	27 Feb 2021 15:32:11
User entered 'No (N)'	System	27 Feb 2021 15:32:11

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-02-27T10:31:59-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd05f5636-fc55-40ec-8870-43dc63892491'	System	27 Feb 2021 15:32:11
User entered 'No (N)'	System	27 Feb 2021 15:32:11

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-02-27T10:32:05-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'd05f5636-fc55-40ec-8870-43dc63892491'	System	27 Feb 2021 15:32:11
User entered '27 Feb 2021 10:32:05'	System	27 Feb 2021 15:32:11

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-03-06T10:54:32-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'b7e44af8-f3f7-4218-bf83-ce76d11b7d99'	System	06 Mar 2021 15:54:42
User entered 'No (N)'	System	06 Mar 2021 15:54:42

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-03-06T10:54:35-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'b7e44af8-f3f7-4218-bf83-ce76d11b7d99'	System	06 Mar 2021 15:54:42
User entered 'No (N)'	System	06 Mar 2021 15:54:42

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-03-06T10:54:40-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'b7e44af8-f3f7-4218-bf83-ce76d11b7d99'	System	06 Mar 2021 15:54:42
User entered '06 Mar 2021 10:54:40'	System	06 Mar 2021 15:54:42

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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 (2a3ad3b9da82c613)', Time: '2021-03-13T07:30:18-06:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'a3d24d47-ee76-4918-869b-b6a864d60132'	System	13 Mar 2021 13:31:11
User entered 'Yes (Y)'	System	13 Mar 2021 13:31:11

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-03-13T07:30:25-06:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'a3d24d47-ee76-4918-869b-b6a864d60132'	System	13 Mar 2021 13:31:11
User entered 'No (N)'	System	13 Mar 2021 13:31:11

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-03-13T07:30:32-06:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'a3d24d47-ee76-4918-869b-b6a864d60132'	System	13 Mar 2021 13:31:11
User entered 'No (N)'	System	13 Mar 2021 13:31:11

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

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 (2a3ad3b9da82c613)', Time: '2021-03-13T07:30:41-06:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'a3d24d47-ee76-4918-869b-b6a864d60132'	System	13 Mar 2021 13:31:11
User entered 'Yes (Y)'	System	13 Mar 2021 13:31:11

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Please 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 (2a3ad3b9da82c613)', Time: '2021-03-13T07:30:48-06:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'a3d24d47-ee76-4918-869b-b6a864d60132'	System	13 Mar 2021 13:31:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Mar 2021 13:31:11

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-03-13T07:30:59-06:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'a3d24d47-ee76-4918-869b-b6a864d60132'	System	13 Mar 2021 13:31:11
User entered '13 Mar 2021 07:30:59'	System	13 Mar 2021 13:31:11

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-03-20T00:17:00-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '3e3c0ccc-ceb4-46dd-8c81-c7517571391f'	System	20 Mar 2021 05:17:12
User entered 'No (N)'	System	20 Mar 2021 05:17:12

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-03-20T00:17:05-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '3e3c0ccc-ceb4-46dd-8c81-c7517571391f'	System	20 Mar 2021 05:17:12
User entered 'No (N)'	System	20 Mar 2021 05:17:12

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-03-20T00:17:09-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '3e3c0ccc-ceb4-46dd-8c81-c7517571391f' User entered '20 Mar 2021 00:17:09'	System	20 Mar 2021 05:17:12
	System	20 Mar 2021 05:17:12

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-03-27T10:31:52-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '4d11bd5c-8a72-42b8-bf0c-f99be1ec839d'	System	27 Mar 2021 15:32:03
User entered 'No (N)'	System	27 Mar 2021 15:32:03

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-03-27T10:31:55-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '4d11bd5c-8a72-42b8-bf0c-f99be1ec839d'	System	27 Mar 2021 15:32:03
User entered 'No (N)'	System	27 Mar 2021 15:32:03

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-03-27T10:31:59-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '4d11bd5c-8a72-42b8-bf0c-f99be1ec839d' User entered '27 Mar 2021 10:31:59'	System	27 Mar 2021 15:32:03
	System	27 Mar 2021 15:32:03

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-04-03T00:03:24-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'cd4f16b6-0f4c-442e-9290-a6449c5d4802'	System	03 Apr 2021 05:03:48
User entered 'No (N)'	System	03 Apr 2021 05:03:48

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-04-03T00:03:27-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'cd4f16b6-0f4c-442e-9290-a6449c5d4802'	System	03 Apr 2021 05:03:48
User entered 'No (N)'	System	03 Apr 2021 05:03:48

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-04-03T00:03:30-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'cd4f16b6-0f4c-442e-9290-a6449c5d4802'	System	03 Apr 2021 05:03:48
User entered '03 Apr 2021 00:03:30'	System	03 Apr 2021 05:03:48

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-04-10T10:31:35-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '9ac0aae6-400e-4f6b-ad7a-55debffd78ed'	System	10 Apr 2021 15:31:51
User entered 'No (N)'	System	10 Apr 2021 15:31:51

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-04-10T10:31:41-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '9ac0aae6-400e-4f6b-ad7a-55debffd78ed'	System	10 Apr 2021 15:31:51
User entered 'No (N)'	System	10 Apr 2021 15:31:51

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-04-10T10:31:45-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '9ac0aae6-400e-4f6b-ad7a-55debffd78ed' User entered '10 Apr 2021 10:31:45'	System	10 Apr 2021 15:31:51
	System	10 Apr 2021 15:31:51

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-04-17T00:54:58-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'ff204ec9-db3a-4138-bd93-5bccf80eff43'	System	17 Apr 2021 05:55:14
User entered 'No (N)'	System	17 Apr 2021 05:55:14

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-04-17T00:55:07-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'ff204ec9-db3a-4138-bd93-5bccf80eff43'	System	17 Apr 2021 05:55:14
User entered 'No (N)'	System	17 Apr 2021 05:55:14

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-04-17T00:55:10-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'ff204ec9-db3a-4138-bd93-5bccf80eff43'	System	17 Apr 2021 05:55:14
User entered '17 Apr 2021 00:55:10'	System	17 Apr 2021 05:55:14

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-04-24T10:36:46-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'e8ab66c1-18e9-4490-936b-6c344dead5ab'	System	24 Apr 2021 15:36:59
User entered 'No (N)'	System	24 Apr 2021 15:36:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-04-24T10:36:50-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'e8ab66c1-18e9-4490-936b-6c344dead5ab'	System	24 Apr 2021 15:36:59
User entered 'No (N)'	System	24 Apr 2021 15:36:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-04-24T10:36:57-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'e8ab66c1-18e9-4490-936b-6c344dead5ab'	System	24 Apr 2021 15:36:59
User entered '24 Apr 2021 10:36:57'	System	24 Apr 2021 15:36:59

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[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 (2a3ad3b9da82c613)', Time: '2021-05-01T10:31:27-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '6d2f9d29-d3fe-4f24-b420-af80f0cf7614'	System	01 May 2021 15:31:56
User entered 'No (N)'	System	01 May 2021 15:31:56

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

Have you been exposed to someone with 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 (2a3ad3b9da82c613)', Time: '2021-05-01T10:31:45-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '6d2f9d29-d3fe-4f24-b420-af80f0cf7614'	System	01 May 2021 15:31:56
User entered 'No (N)'	System	01 May 2021 15:31:56

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-05-01T10:31:54-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: '6d2f9d29-d3fe-4f24-b420-af80f0cf7614'	System	01 May 2021 15:31:56
User entered '01 May 2021 10:31:54'	System	01 May 2021 15:31:56

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:12:05

US3862007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:12:05
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:12:05

US3862007

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:06:10

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 20:51:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-02-27T10:32:17-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'fe03408d-70c0-46fd-a09c-0bc6b0649a8f'	System	27 Feb 2021 15:32:26
User entered 'No (N)'	System	27 Feb 2021 15:32:26

US3862007

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:06:10

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:51:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2a3ad3b9da82c613)', Time: '2021-02-27T10:32:23-05:00', User OID: 'PatientReportedOutcome (US3862007)', ODM File OID: 'fe03408d-70c0-46fd-a09c-0bc6b0649a8f' User entered '27 Feb 2021 10:32:23'	System	27 Feb 2021 15:32:26
	System	27 Feb 2021 15:32:26

US3862007

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:24:42
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 23:31:30

US3862007

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:24:42
User entered '5 Nov 2020'	Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 23:31:30

US3862007

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:24:42
User entered 'Contact Made (CONTACT MADE)'	Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 23:31:30

US3862007

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:24:42
User entered empty.	Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 23:31:30

US3862007

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:24:42
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 23:31:32

US3862007

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:40:22
User entered 'I'	System	05 Nov 2020 23:31:32

US3862007

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	11 Dec 2020 19:18:52

US3862007

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '10 Dec 2020'	Carrie Kibler (b) (4) (b) (4)	11 Dec 2020 19:18:52

US3862007

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Contact Made (CONTACT MADE)'	Carrie Kibler (b) (4) (b) (4)	11 Dec 2020 19:18:52

US3862007

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	11 Dec 2020 19:18:52

US3862007

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	11 Dec 2020 19:18:56

US3862007

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User entered '1'	System	11 Dec 2020 19:18:56

US3862007

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	05 Jan 2021 18:17:24

US3862007

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '05 Jan 2021' reason for change: Data Entry Error	Carrie Kibler (b) (4)	05 Jan 2021 18:17:35
User entered '5 Jan 2021'	Carrie Kibler (b) (4)	05 Jan 2021 18:17:24

US3862007

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Contact Made (CONTACT MADE)'	Carrie Kibler (b) (4) (b) (4)	05 Jan 2021 18:17:24

US3862007

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	05 Jan 2021 18:17:24

US3862007

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	05 Jan 2021 18:17:29

US3862007

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User entered '1'	System	05 Jan 2021 18:17:29

US3862007

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 18:54:57

US3862007

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '09 Feb 2021'	Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 18:54:57

US3862007

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Contact Made (CONTACT MADE)'	Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 18:54:57

US3862007

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 18:54:57

US3862007

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 18:55:01

US3862007

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:35:55
User entered '1'	System	09 Feb 2021 18:55:01

US3862007

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	26 Mar 2021 16:48:59

US3862007

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '22 Mar 2021'	Chanei Henry (b) (4) (b) (4)	26 Mar 2021 16:48:59

US3862007

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Clinic (Clinic)'	Chanei Henry (b) (4) (b) (4)	26 Mar 2021 16:48:59

US3862007

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'VISIT4'	System	26 Mar 2021 16:48:59

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 21:29:50

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '22 Mar 2021'	Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 21:29:50

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '15:14'	Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 21:29:50

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '22 Mar 2021 15:14'	System	30 Mar 2021 21:29:50

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '98.0' F	Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 21:29:50

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Other (Other)'	Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 21:29:50

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'temporal'	Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 21:29:50

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '79'	Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 21:29:50

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'bpm'	System	30 Mar 2021 21:29:50

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '15'	Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 21:29:50

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'breaths/min'	System	30 Mar 2021 21:29:50

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '152'	Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 21:29:50

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'mmHg'	System	30 Mar 2021 21:29:50

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '79'	Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 21:29:50

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'mmHg'	System	30 Mar 2021 21:29:50

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28

US3862007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:10

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28

US3862007

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	26 Mar 2021 16:49:18

US3862007

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '22 Mar 2021'	Chanei Henry (b) (4) (b) (4)	26 Mar 2021 16:49:18

US3862007

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	26 Mar 2021 16:49:32

US3862007

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User closed query 'Per GCL lab Recon: Per Preclarus report, this "Visit 04 Month 7" Immuno sample dated is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 07:59:42
Query 'Per GCL lab Recon: Per Preclarus report, this "Visit 04 Month 7" Immuno sample dated is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' answered with 'Accession Number: 1F67581' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	07 Apr 2021 15:49:33
User opened query 'Per GCL lab Recon: Per Preclarus report, this "Visit 04 Month 7" Immuno sample dated is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 13:51:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '22 Mar 2021'	Chanei Henry (b) (4) (b) (4)	26 Mar 2021 16:49:32

US3862007

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '15:34'	Chanei Henry (b) (4) (b) (4)	26 Mar 2021 16:49:32

US3862007

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered '22 Mar 2021 15:34'	System	26 Mar 2021 16:49:32

US3862007

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	26 Mar 2021 16:49:46

US3862007

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:33:28
User entered 'I'	System	26 Mar 2021 16:49:46

US3862007

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:31
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:31:37
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	05 Apr 2021 22:05:50

US3862007

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:31
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:31:37
User entered '05 Apr 2021'	Sandra Francisco (b) (4) (b) (4)	05 Apr 2021 22:05:50

US3862007

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:31
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:31:37
User entered 'Contact Made (CONTACT MADE)'	Sandra Francisco (b) (4) (b) (4)	05 Apr 2021 22:05:50

US3862007

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:31
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:31:37
User entered empty.	Sandra Francisco (b) (4) (b) (4)	05 Apr 2021 22:05:50

US3862007

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:31
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:31:37
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	05 Apr 2021 22:05:56

US3862007

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:31
User entered '1'	System	05 Apr 2021 22:05:56

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 14:26:08

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '05 Jan 2021' reason for change: Data Entry Error	Carrie Kibler (b) (4)	06 Jan 2021 14:27:29
User entered '5 Jan 2021'	Carrie Kibler (b) (4)	06 Jan 2021 14:26:08

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 14:26:08

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 14:26:08

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:10

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '05 Jan 2021' reason for change: Data Entry Error	Carrie Kibler (b) (4)	06 Jan 2021 14:27:12
User entered '5 Jan 2021'	Carrie Kibler (b) (4)	06 Jan 2021 14:26:21

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:10

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '0'	Carrie Kibler (b) (4)	30 Mar 2021 21:30:00
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 04:51:26

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:10

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 14:26:21

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:10

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Amendment 6 or later (Amendment 6 or later)'	Carrie Kibler (b) (4)	30 Mar 2021 21:30:00
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:51:26

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:10

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '05 Jan 2021' reason for change: Data Entry Error	Carrie Kibler (b) (4)	06 Jan 2021 14:27:12
User entered '5 Jan 2021'	Carrie Kibler (b) (4)	06 Jan 2021 14:26:21

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:10

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'mRNA-1273 (mRNA-1273)'	Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 14:26:21

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:10

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 01:59:26
User entered 'mRNA-1273 (mRNA-1273)'	Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 14:26:21

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:10

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 01:59:26
User entered 'mRNA-1273 (mRNA-1273)'	Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 14:26:21

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:10

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 14:26:21

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:10

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User entered empty.	System	06 Jan 2021 14:26:21

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:10

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User entered empty.	System	06 Jan 2021 14:26:21

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 14:26:37

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '05 Jan 2021' reason for change: Data Entry Error	Carrie Kibler (b) (4)	06 Jan 2021 14:27:00
User entered '5 Jan 2021'	Carrie Kibler (b) (4)	06 Jan 2021 14:26:37

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '11:38'	Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 14:26:37

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User entered '05 Jan 2021 11:38'	System	06 Jan 2021 14:27:00
User entered '5 Jan 2021 11:38'	System	06 Jan 2021 14:26:37

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:06:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 14:26:53

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:06:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '05 Jan 2021'	Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 14:26:53

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:06:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '11:32'	Carrie Kibler (b) (4) (b) (4)	06 Jan 2021 14:26:53

US3862007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:06:10

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:58
User entered '05 Jan 2021 11:32'	System	06 Jan 2021 14:26:53

US3862007

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:06:10

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:33
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 92. Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:38:12
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 215, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:38:09
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 92. Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification.' answered with 'SEE AE: NECK PAIN' (Site from DM).	Thea Marie Cordero (b) (4)	27 Mar 2021 01:33:01
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 215, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'SEE AE : ACUTE KIDNEY INJURY' (Site from DM).	Thea Marie Cordero (b) (4)	27 Mar 2021 01:31:20

US3862007

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:06:10

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 92. Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 04:35:27
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 215, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 04:35:15
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:10:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:49:35
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	02 Oct 2020 00:03:39

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site bruising, LLT: Injection site bruising - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 00:06:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 00:06:54
Data point term sent to Coder	System	02 Oct 2020 00:06:21
User entered 'Injection site bruise'	Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'No (N)'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'No (N)'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'No (N)'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '10 Sep 2020'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '16:48'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User entered '10 Sep 2020 16:48'	System	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'No (N)'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '14 Sep 2020'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 09:08:18
Query 'Data is required. Please provide.' answered with 'end time not known and not clinically significant' (Site from System).	Coni Cheesman (b) (4)	02 Oct 2020 00:05:52
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 00:05:20
User entered empty.	Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User entered empty.	System	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'No (N)'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'Not Related (NOT RELATED)'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'Related (RELATED)'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '1'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Coni Cheesman (b) (4)	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User entered '0'	System	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30
User entered '0'	System	02 Oct 2020 00:05:20

US3862007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:30

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGTT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 15:52:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 15:52:46
Data point term sent to Coder	System	13 Nov 2020 15:51:31
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) NECK PAIN 2) NECK STIFFNESS' (Site from System).	System	13 Nov 2020 15:51:00
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) NECK PAIN 2) NECK STIFFNESS' answered with 'Updated to 1 line' (Site from System).	Shetel Anassi (b) (4)	13 Nov 2020 15:51:00
User entered 'NECK PAIN' reason for change: Data Entry Error	Shetel Anassi (b) (4)	13 Nov 2020 15:50:47
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) NECK PAIN 2) NECK STIFFNESS' (Site from System).	Coder Import (b) (4)	12 Nov 2020 18:29:33
Data point term sent to Coder	System	10 Nov 2020 18:37:58
User entered 'neck pain/stiffness'	Carrie Kibler (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '8 Nov 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User entered empty.	System	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Carrie Kibler (b) (4)	01 Dec 2020 16:35:55
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	10 Nov 2020 18:37:37
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
	(b) (4)	
User entered '11 Nov 2020' reason for change: New Information	Carrie Kibler (b) (4)	01 Dec 2020 16:35:55
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	10 Nov 2020 18:37:37
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User entered empty.	System	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'Not Related (NOT RELATED)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'Not Related (NOT RELATED)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '1'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Carrie Kibler (b) (4)	01 Dec 2020 16:35:55
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Carrie Kibler (b) (4)	10 Nov 2020 18:37:37
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User entered '0'	System	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57
User entered '0'	System	10 Nov 2020 18:37:37

US3862007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:57

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User closed query 'Per CDM Re-query: Site response indicates subject saw doctor and was tested for rhinovirus, however, please note original query is from Medical Monitor specifically asking if subject was assessed for potential Covid-19 infection. As per previous guidance, please clarify if subject was assessed for potential Covid-19 infection, to align with Protocol and v5.0 of CCGs. Please note, Illness visit must be arranged for subject within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection since AE term is a symptom of COVID-19.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:48:44
Comment added 'SEE NARRATIVE NOTE'.	Thea Marie Cordero	22 Mar 2021 21:49:59
Query 'Per CDM Re-query: Site response indicates subject saw doctor and was tested for rhinovirus, however, please note original query is from Medical Monitor specifically asking if subject was assessed for potential Covid-19 infection. As per previous guidance, please clarify if subject was assessed for potential Covid-19 infection, to align with Protocol and v5.0 of CCGs. Please note, Illness visit must be arranged for subject within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection since AE term is a symptom of COVID-19.' answered with 'subject was assessed for potential covid19 subject does not need an illness visit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:08:39

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per CDM Re-query: Site response indicates subject saw doctor and was tested for rhinovirus, however, please note original query is from Medical Monitor specifically asking if subject was assessed for potential Covid-19 infection. As per previous guidance, please clarify if subject was assessed for potential Covid-19 infection, to align with Protocol and v5.0 of CCGs. Please note, Illness visit must be arranged for subject within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection since AE term is a symptom of COVID-19.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 17:31:14
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 05:02:59
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'SUBJECT SAW HER DOCTOR. CAME BACK POSITIVE FOR RHINOVIRUS.' (Site from DM).	Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 18:51:38
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 11:02:55
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral upper respiratory tract infection, LLT: Viral upper respiratory tract infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 22:52:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 22:52:43
Data point term sent to Coder	System	14 Dec 2020 22:51:37
User entered 'VIRAL UPPER RESPIRATORY SYMPTOMS'	Thea Marie Cordero (b) (4)	14 Dec 2020 22:51:03

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '5 Dec 2020'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User entered empty.	System	14 Dec 2020 22:51:03

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '7 Dec 2020'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4)	14 Dec 2020 22:51:03
	Thea Marie Cordero	
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User entered empty.	System	14 Dec 2020 22:51:03

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'Not Related (NOT RELATED)'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'Not Related (NOT RELATED)'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	14 Dec 2020 22:51:03
	Thea Marie Cordero	
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '1'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered '0'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered empty.	(b) (4) Thea Marie Cordero	14 Dec 2020 22:51:03
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'CLARIFICATION REGARDING AE: SUBJECT HAD MILD INTERMITTENT NASAL CONGESTION, RHINORRHEA AND SORE THROAT FROM 05 -07 DEC 2020. EXPOSED TO RELATIVE WHO HAD RHINOVIRUS. TOOK ALKA SELTZER COLD AND FLU MEDICATIONS. SUBJECT DID NOT CALL SITE OR REPORT SYMPTOMS IN EDIARY. ILLNESS VISIT NOT DONE. PROTOCOL DEVIATION CREATED' reason for change: New Information	(b) (4) Thea Marie Cordero	22 Mar 2021 21:56:45
User entered 'SUBJECT HAD CONTACT WITH A FAMILY MEMBER WHO TESTED POSITIVE FOR RHINOVIRUS.' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 18:52:38
User entered empty.	Thea Marie Cordero (b) (4)	14 Dec 2020 22:51:03

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User entered '0'	System	14 Dec 2020 22:51:03

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56
User entered '0'	System	14 Dec 2020 22:51:03

US3862007

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:29:56

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:53:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:08:28
User entered 'USA-US121-2021-mRNA-1273-P301000005'	System	15 Mar 2021 14:08:18
User entered 'New'	(b) (4), (b) (6)	15 Mar 2021 14:08:18

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:53:06
User coded data point as SOC: Renal and urinary disorders, HLG: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 15:41:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 15:41:45
Data point term sent to Coder	System	12 Mar 2021 15:40:49
User entered 'ACUTE KIDNEY INJURY'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:53:09
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:53:12
User entered 'No (N)'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:53:13
User entered 'No (N)'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:53:17
User entered '11 Mar 2021'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:53:19
User entered empty.	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:45:57
User closed query 'Per progress notes in source, subject's symptoms have resolved as of 14Mar21. Please review and update.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6)	14 Apr 2021 21:45:56
Query 'Per progress notes in source, subject's symptoms have resolved as of 14Mar21. Please review and update.' answered with 'data updated ' (Site from CRA).	Thea Marie Cordero (b) (4) (b) (4), (b) (6)	29 Mar 2021 14:20:58 22 Mar 2021 16:59:16
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	22 Mar 2021 16:57:49
User opened query 'Per progress notes in source, subject's symptoms have resolved as of 14Mar21. Please review and update.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 16:02:11
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:46:10
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
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 Mar 2021 14:12:44
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	22 Mar 2021 21:23:12
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	22 Mar 2021 21:23:12
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 'PENDING MEDICAL REDORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	22 Mar 2021 21:22:38
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	22 Mar 2021 16:57:49
User entered '14 Mar 2021' reason for change: New Information	(b) (4), (b) (6)	22 Mar 2021 16:57:49

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, end date (dd MMM yyyy)

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)	22 Mar 2021 13:19:55
User entered empty.	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:02:36
User entered empty.	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:53:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:53:26
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	12 Mar 2021 15:40:31
User entered 'Yes (Y)' reason for change: New Information	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:31
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	12 Mar 2021 15:40:00
User entered 'No (N)'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

Death

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:53:29
User entered '0'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:53:30
User entered '0'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	22 Mar 2021 16:57:49
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	22 Mar 2021 16:57:49
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:53:33
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	12 Mar 2021 15:40:00
User entered '1'	Thea Marie Cordero	12 Mar 2021 15:40:00
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:53:35
User entered '11 Mar 2021'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:46:31
User closed query 'Per progress notes in source, subject was discharged home on 14Mar21. Please review and update.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6)	14 Apr 2021 21:46:27
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	Thea Marie Cordero (b) (4)	29 Mar 2021 14:20:58
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 14:12:57
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'PENDING MEDICAL RECORDS' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 14:12:53
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'UPDATED IN SOURCE DOCUMENT AND EDC' (Site from Safety).	Thea Marie Cordero (b) (4)	22 Mar 2021 21:21:48
Query 'Per progress notes in source, subject was discharged home on 14Mar21. Please review and update.' answered with 'UPDATED IN SOURCE DOCUMENT AND EDC' (Site from CRA).	Thea Marie Cordero (b) (4)	22 Mar 2021 21:20:00
User entered '14 Mar 2021' reason for change: New Information	Thea Marie Cordero (b) (4)	22 Mar 2021 21:19:55
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 16:57:49
	(b) (4), (b) (6)	22 Mar 2021 13:22:28

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:19:30
User opened query 'Per progress notes in source, subject was discharged home on 14Mar21. Please review and update.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 15:55:27
User entered empty.	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:46:34
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	12 Mar 2021 15:40:00
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:02:45
User entered empty.	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:54:10
User entered '0'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:54:12
User entered '0'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:54:17
User entered '0'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:54:08
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:54:18
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:54:20
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

None

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:54:24
User entered '0'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Please enter con-meds that were used to treat. Per source notes, IV hydration was given.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6)	19 Apr 2021 21:28:40
Query 'Please enter con-meds that were used to treat. Per source notes, IV hydration was given.' answered with 'PENDING MEDICAL RECORDS' (Site from CRA).	Thea Marie Cordero (b) (4)	29 Mar 2021 14:20:58
User opened query 'Please enter con-meds that were used to treat. Per source notes, IV hydration was given.' (Site from CRA). User entered '1'	Thea Marie Cordero (b) (4)	22 Mar 2021 21:24:00
	(b) (4), (b) (6)	17 Mar 2021 16:17:54
	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User closed query 'PV Query: Please provide dates of Creatinine level and GFR together with normal ranges for each' (Site from Safety).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:13:06
User closed query 'PV Query: Please provide dates of brain MRI and brain CT scan' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 14:13:03
Query 'PV Query: Please provide dates of Creatinine level and GFR together with normal ranges for each' answered with 'PENDING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	22 Mar 2021 21:26:25
Query 'PV Query: Please provide dates of brain MRI and brain CT scan' answered with 'PENDING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	22 Mar 2021 21:24:12
DataPoint Un-verified.	(b) (4), (b) (6)	22 Mar 2021 16:57:49
User entered '1' reason for change: New Information	(b) (4), (b) (6)	22 Mar 2021 16:57:49
User opened query 'PV Query: Please provide dates of Creatinine level and GFR together with normal ranges for each' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:20:31
User opened query 'PV Query: Please provide dates of brain MRI and brain CT scan' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:20:14
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:54:28
User entered '0'	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:46:55
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	22 Mar 2021 21:23:12
New Information	Thea Marie Cordero	22 Mar 2021 21:23:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:05:14
User entered empty.	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
	(b) (4)	
DataPoint Un-verified.	Thea Marie Cordero	12 Apr 2021 22:11:13
	(b) (4)	
Signature has been broken.	Thea Marie Cordero	12 Apr 2021 22:11:13
	(b) (4)	

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Narrative](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273-P301 SUBJECT: US3862007 67 YEARS OLD CAUCASIAN FEMALE MEDICAL HISTORY: TYPE 2 DM, HYPERLIPIDEMIA, HYPOTHYROIDISM, SEASONAL ALLERGIES, OSTEOARTHRITIS MEDICATION: METFORMIN, SIMVASTATIN, LEVOXYL, IBUPROFEN, CELEBREX AMENDMENT 6 PROTOCOL UNBLINDED: 05 JAN 2021 RANDOMIZED TREATMENT ARM: MRNA 1273 FIRST DOSE: 13 AUG 2020 SECOND DOSE: 10 SEP 2020 11 MAR 2021: SUBJECT CALLED SITE TO RESCHEDULE HER VISIT 4 SINCE SHE WAS NOT FEELING WELL. REPORTED WAKING UP WITH A STRANGE SENSATION IN HER HEAD, FEELING OF THICK SENSATION IN HER TONGUE WITH DIFFICULTY PRONOUNCING SOME WORDS. NOTED MILD SLURRING AND DRAGGING OF WORDS DURING OUR CONVERSATION. SUBJECT WAS INSTRUCTED RIGHT AWAY TO SEEK IMMEDIATE MEDICAL HELP (CALL 911). 12 MARCH 2021: FOLLOW-UP PHONE CALL. SUBJECT REPORTED THAT SHE WAS ADMITTED IN THE HOSPITAL SINCE YESTERDAY (11 MAR 2021). CT SCAN OF BRAIN AND MRI OF BRAIN: NO SIGNIFICANT FINDINGS. BLOOD WORK UP REVEALED: CREATININE LEVEL 3.4 MG/DL, GFR LEVEL 15 ML/MIN. CURRENTLY RECEIVING INTRAVENOUS HYDRATION. SUBJECT WILL BE FOLLOWED UP CLOSELY. MEDICAL RECORDS WILL BE REQUESTED ONCE DISCHARGED FROM THE HOSPITAL. 12 APR 2021: SUBJECT PRESENTED WITH ACUTE ONSET OF TRANSIENT SLURRED SPEECH AND RIGHT LEG WEAKNESS. CT BRAIN- NEGATIVE, MRI BRAIN-NEGATIVE, NEUROLOGIST DETERMINED NEUROLOGICAL ISSUES RELATED TO ACUTE	Thea Marie Cordero (b) (4)	12 Apr 2021 22:11:13

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Narrative](#)

Audit	User	Time (GMT)
KIDNEY INJURY. MRA HEAD AND NECK- POSSIBLE ANEURYSM 2-3MM LEFT UPPER INTERNAL CAROTID ARTERY. CARDIOLOGIST RECOMMENDATION-NO INTERVENTION, FOLLOW-UP ANNUAL IMAGING.ACUTE KIDNEY INJURY DETERMINED RELATED TO NSAIDS USE. CELEBREX, IBUPROFEN AND VITAMIN D DISCONTINUED. TREATMENT- IV HYDRATION OF NORMAL SALINE SOLUTION. BASELINE CREATININE 3.97 IMPROVED TO 1.8 MG/DL.' reason for change: New Information User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:20:58
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:13:10
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'PENDING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	22 Mar 2021 21:27:00
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:19:07
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:17:17
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Mar 2021 21:55:16
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	12 Mar 2021 21:55:16

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Narrative](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273-P301 Subject: US3862007 67 years old Caucasian female Medical History: Type 2 DM, Hyperlipidemia, Hypothyroidism, Seasonal Allergies, Osteoarthritis Medication: Metformin, Simvastatin, Levoxyl, Ibuprofen, Celebrex Amendment 6 Protocol Unblinded: 05 Jan 2021 Randomized Treatment Arm: mRNA 1273 First dose: 13 Aug 2020 Second dose: 10 Sep 2020 11 Mar 2021: Subject called site to reschedule her Visit 4 since she was not feeling well. Reported waking up with a strange sensation in her head, feeling of thick sensation in her tongue with difficulty pronouncing some words. Noted mild slurring and dragging of words during our conversation. Subject was instructed right away to seek immediate medical help (call 911). 12 March 2021: Follow-up phone call. Subject reported that she was admitted in the hospital since yesterday (11 Mar 2021). CT Scan of brain and MRI of brain: no significant findings. Blood work up revealed: Creatinine level 3.4 mg/dl, GFR level 15 mL/min. Currently receiving intravenous hydration. Subject will be followed up closely. Medical records will be requested once discharged from the hospital.' reason for change: New Information	Thea Marie Cordero (b) (4)	12 Mar 2021 21:55:16
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Mar 2021 15:40:31
User entered empty.	Thea Marie Cordero (b) (4)	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	12 Mar 2021 15:40:31
User entered '0'	System	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:06:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 15:40:00

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 13:08:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 13:08:58
Data point term sent to Coder	System	12 Apr 2021 21:41:30
User entered 'URRINARY TRACT INFECTION'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '11 Mar 2021'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User entered empty.	System	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '25 Mar 2021'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User entered empty.	System	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '1'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User entered '0'	System	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04
User entered '1'	System	12 Apr 2021 21:41:12

US3862007

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:06:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:30:04

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLG: Central nervous system vascular disorders, HLT: Central nervous system aneurysms and dissections, PT: Carotid artery aneurysm, LLT: Carotid artery aneurysm - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 11:42:00
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 11:42:00
	(b) (4)	
Data point term sent to Coder	System	12 Apr 2021 21:43:39
User entered 'SUSPECTED INTERNAL CAROTID ARTERY ANEURYSM'	(b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

Death

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

None

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '1'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 21:42:52

US3862007

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:06:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 21:42:52

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:06:10

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:33
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User closed query 'Per CDM Re-Query: Site response noted; however, please update data of CM for AE "Acute Kidney Injury" when available. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 12:23:05
Query 'Per CDM Re-Query: Site response noted; however, please update data of CM for AE "Acute Kidney Injury" when available. Thank you.' answered with 'UPDATED IN SOURCE DOCUMENT AND EDC' (Site from DM).	Thea Marie Cordero (b) (4)	13 Apr 2021 15:24:21
User opened query 'Per CDM Re-Query: Site response noted; however, please update data of CM for AE "Acute Kidney Injury" when available. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:57:29
User closed query 'Per CDM: Please verify data and add CM for AE 'Acute Kidney Injury' as CM is selected for 'Other Action Taken' on AE form. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:57:29
Query 'Per CDM: Please verify data and add CM for AE 'Acute Kidney Injury' as CM is selected for 'Other Action Taken' on AE form. Thank you.' answered with 'pending medical records ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 19:42:13
User opened query 'Per CDM: Please verify data and add CM for AE 'Acute Kidney Injury' as CM is selected for 'Other Action Taken' on AE form. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 20:52:45
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:18:02
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 17:21:33

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 17:25:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 17:25:24
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 17:24:08
User entered 'Metformin'	Coni Cheesman (b) (4)	13 Aug 2020 17:23:14
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 17:23:14
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Type 2 Diabetes'	Coni Cheesman (b) (4)	13 Aug 2020 17:23:14
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '1'	Coni Cheesman (b) (4)	13 Aug 2020 17:23:14
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'g (g)'	Coni Cheesman (b) (4)	13 Aug 2020 17:23:14
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:23:14
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'twice daily (BID)'	Coni Cheesman (b) (4)	13 Aug 2020 17:23:14
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:23:14
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Oral (ORAL)'	Coni Cheesman (b) (4)	13 Aug 2020 17:23:14
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:23:14
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 00:56:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 18:02:07
User entered 'UN UNK 2015'	Coni Cheesman (b) (4)	13 Aug 2020 17:23:14

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 17:23:14
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 17:23:14
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:23:14
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 17:23:14
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 17:23:14

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:23:14

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 17:23:14

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 17:28:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Aug 2020 17:28:23
Data point term sent to Coder User entered 'Colace'	System Coni Cheesman (b) (4)	13 Aug 2020 17:27:12 13 Aug 2020 17:27:06

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 17:27:06
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Constipation'	Coni Cheesman (b) (4)	13 Aug 2020 17:27:06
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '100'	Coni Cheesman (b) (4)	13 Aug 2020 17:27:06
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'mg (mg)'	Coni Cheesman (b) (4)	13 Aug 2020 17:27:06
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:27:06
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'twice daily (BID)'	Coni Cheesman (b) (4)	13 Aug 2020 17:27:06
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:27:06
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Oral (ORAL)'	Coni Cheesman (b) (4)	13 Aug 2020 17:27:06
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:27:06
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 00:56:41
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 18:02:07
User entered 'UN UNK 2017'	Coni Cheesman (b) (4)	13 Aug 2020 17:27:06

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 17:27:06
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 17:27:06
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:27:06
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 17:27:06
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 17:27:06

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:27:06

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 17:27:06

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Aug 2020 03:44:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 03:44:14
Data point term sent to Coder	System	13 Aug 2020 17:50:00
User entered 'Vitamin C'	Coni Cheesman (b) (4) (b) (4)	13 Aug 2020 17:49:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 17:49:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Prophylaxis for nutritional deficiency'	Coni Cheesman (b) (4)	13 Aug 2020 17:49:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '1'	Coni Cheesman (b) (4)	13 Aug 2020 17:49:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'g (g)'	Coni Cheesman (b) (4)	13 Aug 2020 17:49:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:49:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'once daily (QD)'	Coni Cheesman (b) (4)	13 Aug 2020 17:49:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:49:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Oral (ORAL)'	Coni Cheesman (b) (4)	13 Aug 2020 17:49:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:49:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 00:56:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 18:02:07
User entered 'UN UNK 2018'	Coni Cheesman (b) (4)	13 Aug 2020 17:49:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 17:49:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 17:49:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:49:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 17:49:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:49:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:49:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 17:49:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE, PRODUCTSYNONYM: IRON SULFATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 17:53:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 17:53:29
Data point term sent to Coder	System	13 Aug 2020 17:52:05
User entered 'Iron Sulfate'	Coni Cheesman (b) (4) (b) (4)	13 Aug 2020 17:51:57

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 17:51:57
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Prophylaxis for nutritional deficiency'	Coni Cheesman (b) (4)	13 Aug 2020 17:51:57
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '650'	Coni Cheesman (b) (4)	13 Aug 2020 17:51:57
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'mg (mg)'	Coni Cheesman (b) (4)	13 Aug 2020 17:51:57
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:51:57
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'once daily (QD)'	Coni Cheesman (b) (4)	13 Aug 2020 17:51:57
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:51:57
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Oral (ORAL)'	Coni Cheesman (b) (4)	13 Aug 2020 17:51:57
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:51:57
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 00:56:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 18:02:07
User entered 'UN UNK 2017'	Coni Cheesman (b) (4)	13 Aug 2020 17:51:57

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 17:51:57
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 17:51:57
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:51:57
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 17:51:57
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:51:57

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:51:57

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 17:51:57

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 17:55:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 17:55:20
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 17:54:10
User entered 'Zyrtec'	Coni Cheesman (b) (4)	13 Aug 2020 17:53:21
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 17:53:21
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Seasonal allergies'	Coni Cheesman (b) (4)	13 Aug 2020 17:53:21
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '10'	Coni Cheesman (b) (4)	13 Aug 2020 17:53:21
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'mg (mg)'	Coni Cheesman (b) (4)	13 Aug 2020 17:53:21
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:53:21

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 17:53:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 17:53:47
User entered 'once daily (QD)' reason for change: New Information	Coni Cheesman (b) (4)	13 Aug 2020 17:53:47
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 17:53:21
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:53:21

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:53:21
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Oral (ORAL)'	Coni Cheesman (b) (4)	13 Aug 2020 17:53:21
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:53:21
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 00:56:53
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 18:02:07
User entered 'UN UNK 2018'	Coni Cheesman (b) (4)	13 Aug 2020 17:53:21

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 17:53:21
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 17:53:21

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:53:21

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 17:53:21

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:53:47
User entered empty.	System	13 Aug 2020 17:53:21

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:53:47
User entered empty.	System	13 Aug 2020 17:53:21

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 17:53:47
User entered empty.	System	13 Aug 2020 17:53:21

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
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.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 22:11:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 22:11:20
Data point term sent to Coder	System	13 Aug 2020 17:56:19
User entered 'Aspirin'	Coni Cheesman (b) (4) (b) (4)	13 Aug 2020 17:55:47

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 17:55:47
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Superficial thrombosis'	Coni Cheesman (b) (4)	13 Aug 2020 17:55:47
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '81'	Coni Cheesman (b) (4)	13 Aug 2020 17:55:47
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'mg (mg)'	Coni Cheesman (b) (4)	13 Aug 2020 17:55:47

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:55:47

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'once daily (QD)'	Coni Cheesman (b) (4)	13 Aug 2020 17:55:47
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:55:47
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Oral (ORAL)'	Coni Cheesman (b) (4)	13 Aug 2020 17:55:47
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:55:47
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 00:56:57
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 18:02:07
User entered '01 Jul 2020'	Coni Cheesman (b) (4)	13 Aug 2020 17:55:47

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 17:55:47
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 17:55:47
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:55:47

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 17:55:47

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:55:47

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:55:47

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 17:55:47

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 17:58:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 17:58:31
Data point term sent to Coder	System	13 Aug 2020 17:57:22
User entered 'Simvastatin'	Coni Cheesman (b) (4) (b) (4)	13 Aug 2020 17:57:10

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 17:57:10
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Hyperlipidemia'	Coni Cheesman (b) (4)	13 Aug 2020 17:57:10
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '20'	Coni Cheesman (b) (4)	13 Aug 2020 17:57:10
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'mg (mg)'	Coni Cheesman (b) (4)	13 Aug 2020 17:57:10
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:57:10
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'once daily (QD)'	Coni Cheesman (b) (4)	13 Aug 2020 17:57:10
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:57:10
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Oral (ORAL)'	Coni Cheesman (b) (4)	13 Aug 2020 17:57:10

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:57:10

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 00:57:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 18:02:07
User entered 'UN UNK 2015'	Coni Cheesman (b) (4)	13 Aug 2020 17:57:10

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 17:57:10
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	13 Aug 2020 17:57:10
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 17:57:10

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 17:57:10
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:57:10

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:57:10

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 17:57:10

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOETHYROXINE SODIUM, PRODUCTSYNONYM: LEVOXYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 18:02:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:02:27
Data point term sent to Coder	System	13 Aug 2020 18:01:28
User entered 'Levoxyl'	Coni Cheesman (b) (4) (b) (4)	13 Aug 2020 18:00:46

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	13 Aug 2020 18:00:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Hypothyroidism'	Coni Cheesman (b) (4)	13 Aug 2020 18:00:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '112'	Coni Cheesman (b) (4)	13 Aug 2020 18:00:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	06 Nov 2020 15:45:15
	(b) (4)	
User entered 'Other (OTHER)'	Coni Cheesman (b) (4)	13 Aug 2020 18:00:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User closed query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:43:50
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. answered with 'Data corrected' (Site from DM).	Shetel Anassi (b) (4)	06 Nov 2020 15:45:23
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4)	06 Nov 2020 15:45:15
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:19:18
User entered 'mcg'	Coni Cheesman (b) (4)	13 Aug 2020 18:00:46

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'once daily (QD)'	Coni Cheesman (b) (4)	13 Aug 2020 18:00:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 18:00:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Oral (ORAL)'	Coni Cheesman (b) (4)	13 Aug 2020 18:00:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 18:00:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 00:57:05
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 18:02:07
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 18:01:18
User entered 'UN UNK 1985' reason for change: Data Entry Error	Coni Cheesman (b) (4)	13 Aug 2020 18:01:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 18:00:46
User entered 'un ' (non-conformant).	Coni Cheesman (b) (4)	13 Aug 2020 18:00:46

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '0'	Coni Cheesman (b) (4)	13 Aug 2020 18:00:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:01:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:01:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Coni Cheesman (b) (4)	13 Aug 2020 18:01:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:00:46
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 18:00:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 18:00:46

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:01:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 18:01:18
User entered 'No (N)' reason for change: Data Entry Error	Coni Cheesman (b) (4)	13 Aug 2020 18:01:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:00:46
User entered empty.	Coni Cheesman (b) (4)	13 Aug 2020 18:00:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 18:00:46

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 18:00:46

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 18:00:46

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALTREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 19:01:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 19:01:23
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 19:00:49
Data point term sent to Coder	System	13 Aug 2020 18:59:48
User entered 'valtrex'	Carrie Kibler (b) (4)	13 Aug 2020 18:59:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 18:59:46

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'genital herpes'	Carrie Kibler (b) (4)	13 Aug 2020 18:59:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '2'	Carrie Kibler (b) (4)	13 Aug 2020 18:59:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:00:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 19:00:28
User entered 'g (g)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Aug 2020 19:00:28
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:59:46
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 18:59:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 18:59:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:00:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 19:00:28
User entered 'as needed (PRN)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Aug 2020 19:00:28
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:59:46
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 18:59:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 18:59:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:00:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 19:00:28
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Aug 2020 19:00:28
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:59:46
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 18:59:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 18:59:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 00:57:08
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:00:28
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	13 Aug 2020 19:00:28
User entered 'un UNK 2014' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Aug 2020 19:00:28
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	13 Aug 2020 18:59:46
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 18:59:46

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	13 Aug 2020 18:59:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:00:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 19:00:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Aug 2020 19:00:28
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:59:46
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 18:59:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 18:59:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:00:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 19:00:28
User entered 'No (N)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Aug 2020 19:00:28
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 18:59:46
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 18:59:46
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 18:59:46

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 18:59:46

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 18:59:46

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 19:12:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 19:12:23
Data point term sent to Coder	System	13 Aug 2020 19:11:15
User entered 'Vitamin d3'	Carrie Kibler (b) (4)	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'general health'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '5000'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'IU (IU)'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'once daily (QD)'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 00:57:12
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:10:31
User entered 'un Mar 2020'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '0'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
Signature has been broken.	Thea Marie Cordero (b) (4)	12 Apr 2021 22:00:01
User entered 'No (N)' reason for change: New Information	Thea Marie Cordero (b) (4)	12 Apr 2021 22:00:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
Signature has been broken.	Thea Marie Cordero (b) (4)	12 Apr 2021 22:00:01
User entered '12 Mar 2021' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	12 Apr 2021 22:00:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:10:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 19:10:38
User entered 'No (N)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Aug 2020 19:10:38
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:10:31
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User entered '1'	System	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User entered '1'	System	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:09
User entered '804 (804)'	System	13 Aug 2020 19:10:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 19:13:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 19:13:39
Data point term sent to Coder	System	13 Aug 2020 19:12:19
User entered 'zinc'	Carrie Kibler (b) (4)	13 Aug 2020 19:11:28

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:11:28

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'general health'	(b) (4) Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:11:28

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '25'	(b) (4) Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:11:28

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'mg (mg)'	Carrie Kibler (b) (4)	13 Aug 2020 19:11:28
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 19:11:28
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	13 Aug 2020 19:11:28
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 19:11:28
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Oral (ORAL)'	(b) (4) Carrie Kibler (b) (4)	13 Aug 2020 19:11:28
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 19:11:28
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 00:57:16
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:11:28
User entered 'un Mar 2020'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:11:28

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	13 Aug 2020 19:11:28
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:11:28

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 19:11:28
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:11:28

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:11:28

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:11:28

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:11:28

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 19:13:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:13:38
Data point term sent to Coder	System	13 Aug 2020 19:12:21
User entered 'melatonin'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:12:11

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	13 Aug 2020 19:12:11
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'sleep aide'	Carrie Kibler (b) (4)	13 Aug 2020 19:12:11
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '10'	Carrie Kibler (b) (4)	13 Aug 2020 19:12:11
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'mg (mg)'	Carrie Kibler (b) (4)	13 Aug 2020 19:12:11
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 19:12:11
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'as needed (PRN)'	Carrie Kibler (b) (4)	13 Aug 2020 19:12:11
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 19:12:11
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	13 Aug 2020 19:12:11
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 19:12:11
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 00:57:20
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:12:11
User entered 'un UNK 2017'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:12:11

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	13 Aug 2020 19:12:11
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	13 Aug 2020 19:12:11
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 19:12:11
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	13 Aug 2020 19:12:11
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:12:11

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:12:11

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 19:12:11

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 19:15:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:15:08
Data point term sent to Coder	System	13 Aug 2020 19:13:38
User entered 'ibuprofen'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:12:45

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	13 Aug 2020 19:12:45
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'osteoarthritis'	(b) (4) Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:12:45

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '600'	(b) (4) Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:12:45

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'mg (mg)'	Carrie Kibler (b) (4)	13 Aug 2020 19:12:45
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 19:12:45
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	13 Aug 2020 19:12:45
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 19:12:45
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Oral (ORAL)'	(b) (4) Carrie Kibler (b) (4)	13 Aug 2020 19:12:45
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 19:12:45
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 00:57:24
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:12:45
User entered 'un UNK 1980'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:12:45

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	13 Aug 2020 19:12:45
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
	(b) (4)	
Signature has been broken.	Thea Marie Cordero	12 Apr 2021 21:58:12
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Thea Marie Cordero	12 Apr 2021 21:58:12
	(b) (4)	
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	13 Aug 2020 19:12:45
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
	(b) (4)	
Signature has been broken.	Thea Marie Cordero	12 Apr 2021 21:58:12
	(b) (4)	
User entered '12 Mar 2021' reason for change: New Information	Thea Marie Cordero	12 Apr 2021 21:58:12
	(b) (4)	
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 19:12:45
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	13 Aug 2020 19:12:45
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:12:45

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:12:45

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:12:45

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 19:15:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Aug 2020 19:15:09
Data point term sent to Coder	System	13 Aug 2020 19:13:40
User entered 'multivitamin'	Carrie Kibler (b) (4)	13 Aug 2020 19:13:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	13 Aug 2020 19:13:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'general health'	Carrie Kibler (b) (4)	13 Aug 2020 19:13:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '1'	Carrie Kibler (b) (4)	13 Aug 2020 19:13:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'tablet (TABLET)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:13:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 19:13:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	13 Aug 2020 19:13:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 19:13:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	13 Aug 2020 19:13:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 19:13:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 00:57:28
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:13:31
User entered 'un UNK 2015'	Carrie Kibler (b) (4) (b) (4)	13 Aug 2020 19:13:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	13 Aug 2020 19:13:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	13 Aug 2020 19:13:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Aug 2020 19:13:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	13 Aug 2020 19:13:31
	(b) (4)	

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:13:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:13:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:13:31

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STERIODS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 00:08:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 00:08:56
Data point term sent to Coder	System	02 Oct 2020 00:08:24
User entered 'Voltaren gel'	Coni Cheesman (b) (4)	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Coni Cheesman (b) (4)	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Osteoarthritis'	Coni Cheesman (b) (4)	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '2'	Coni Cheesman (b) (4)	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'g (g)'	Coni Cheesman (b) (4)	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Coni Cheesman (b) (4)	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'as needed (PRN)'	Coni Cheesman (b) (4)	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Coni Cheesman (b) (4)	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Topical (TOPICAL)'	Coni Cheesman (b) (4)	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Coni Cheesman (b) (4)	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '28 Sep 2020'	Coni Cheesman (b) (4)	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '0'	Coni Cheesman (b) (4)	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Coni Cheesman (b) (4)	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '28 Sep 2020'	Coni Cheesman (b) (4)	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Coni Cheesman (b) (4)	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User entered empty.	System	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User entered empty.	System	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:13
User entered empty.	System	02 Oct 2020 00:07:50

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 00:09:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 00:09:57
Data point term sent to Coder	System	02 Oct 2020 00:09:25
User entered 'Celebrex'	Coni Cheesman (b) (4)	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Coni Cheesman (b) (4)	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 09:59:09
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' answered with 'PART OF PMHX AND TAKES PAIN MEDS FOR IT AS NEEDED.' (Site from DM).	Carrie Kibler (b) (4) (b) (4)	01 Dec 2020 16:41:50
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 11:12:23
User entered 'Osteoarthritis'	Coni Cheesman (b) (4)	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '200'	Coni Cheesman (b) (4)	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'mg (mg)'	Coni Cheesman (b) (4)	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Coni Cheesman (b) (4)	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'once daily (QD)'	Coni Cheesman (b) (4)	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Coni Cheesman (b) (4)	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Oral (ORAL)'	Coni Cheesman (b) (4)	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Coni Cheesman (b) (4)	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '28 Sep 2020'	Coni Cheesman (b) (4)	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '0'	Coni Cheesman (b) (4)	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)' reason for change: New Information	Carrie Kibler (b) (4)	06 Oct 2020 20:37:47
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '5 Oct 2020' reason for change: New Information	Carrie Kibler (b) (4)	06 Oct 2020 20:37:47
User entered empty.	Coni Cheesman (b) (4)	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Coni Cheesman (b) (4)	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User entered '1'	System	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User entered '1'	System	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:39
User entered '804 (804)'	System	02 Oct 2020 00:08:59

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:39:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:39:20
Data point term sent to Coder	System	06 Oct 2020 20:38:27
User entered 'celebrex'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'osteoarthritis'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '200'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'mg (mg)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'as needed (PRN)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '6 Oct 2020'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '0'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
Signature has been broken.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:59:08
User entered 'No (N)' reason for change: New Information	Thea Marie Cordero (b) (4)	12 Apr 2021 21:59:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
Signature has been broken.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:59:08
User entered '12 Mar 2021' reason for change: New Information	Thea Marie Cordero (b) (4)	12 Apr 2021 21:59:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User entered empty.	System	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User entered empty.	System	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:43
User entered empty.	System	06 Oct 2020 20:38:19

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: FLUZONE [INFLUENZA VACCINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 23:31:25
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 Oct 2020 23:31:25
Data point term sent to Coder	System	06 Oct 2020 20:39:30
User entered 'flu vaccine, fluzone'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'prevention of influenza'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '0.5'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'mL (mL)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'once (ONCE)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Intramuscular (INTRAMUSCULAR)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '2 Oct 2020'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '0'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '2 Oct 2020'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User entered empty.	System	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User entered empty.	System	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:47
User entered empty.	System	06 Oct 2020 20:39:16

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: OTHER TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, PRODUCT: MENTHOL, PRODUCTSYNONYM: BIOFREEZE [MENTHOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 21:49:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 21:49:39
Data point term sent to Coder	System	11 Dec 2020 20:38:14
User closed query 'CDM-Coding: For Coding Purpose, Please update the medication by providing the active/generic ingredients.' (Site from System).	System	11 Dec 2020 20:37:36
Query 'CDM-Coding: For Coding Purpose, Please update the medication by providing the active/generic ingredients.' answered with 'data entered' (Site from System).	Trent Davis (b) (4) (b) (4)	11 Dec 2020 20:37:36
User entered 'BIOFREEZE ROLL-ON Menthol 3.5%' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	11 Dec 2020 20:37:27
User opened query 'CDM-Coding: For Coding Purpose, Please update the medication by providing the active/generic ingredients.' (Site from System).	Coder Import (b) (4) (b) (4)	11 Dec 2020 04:07:44
Data point term sent to Coder	System	01 Dec 2020 16:39:21
Coding entries removed.	Carrie Kibler (b) (4) (b) (4)	01 Dec 2020 16:39:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: OTHER TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, PRODUCT: MENTHOL, PRODUCTSYNONYM: BIOFREEZE [MENTHOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:49:43

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. Data point term sent to Coder User entered 'biofreeze roll-on'	Coder Import (b) (4) (b) (4) System Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 21:49:43 10 Nov 2020 18:18:26 10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'NECK PAIN' reason for change: Data Entry Error	Carrie Kibler (b) (4)	01 Dec 2020 16:39:16
User entered 'neck pain/stiffness'	Carrie Kibler (b) (4)	10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '1'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Other (OTHER)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'application' reason for change: Data Entry Error	Carrie Kibler (b) (4)	10 Dec 2020 20:31:02
User entered 'roll'	Carrie Kibler (b) (4)	10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'as needed (PRN)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Topical (TOPICAL)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '8 Nov 2020'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '0'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)' reason for change: New Information	Carrie Kibler (b) (4)	01 Dec 2020 15:48:51
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '10 Nov 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	01 Dec 2020 15:49:39
User entered '11 Nov 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	01 Dec 2020 15:48:51
User entered empty.	Carrie Kibler (b) (4)	10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User entered empty.	System	10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User entered empty.	System	10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:51
User entered empty.	System	10 Nov 2020 18:18:23

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 16:40:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 16:40:55
Data point term sent to Coder Coding entries removed.	System Carrie Kibler (b) (4) (b) (4)	01 Dec 2020 16:39:21 01 Dec 2020 16:38:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:54:32
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 Nov 2020 14:54:32
Data point term sent to Coder User entered 'ibuprofen'	System Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:27 10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'NECK PAIN' reason for change: Data Entry Error	Carrie Kibler (b) (4)	01 Dec 2020 16:38:59
User entered 'neck pain/stiffness'	Carrie Kibler (b) (4)	10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '600'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'mg (mg)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'once (ONCE)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '8 Nov 2020'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '0'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '8 Nov 2020'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User entered empty.	System	10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User entered empty.	System	10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:56
User entered empty.	System	10 Nov 2020 18:19:03

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 16:40:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 16:40:54
Data point term sent to Coder Coding entries removed.	System Carrie Kibler (b) (4) (b) (4)	01 Dec 2020 16:39:23 01 Dec 2020 16:39:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:54:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:54:33
Data point term sent to Coder User entered 'ibuprofen'	System Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:20:28 10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'NECK PAIN' reason for change: Data Entry Error	Carrie Kibler (b) (4)	01 Dec 2020 16:39:07
User entered 'neck pain/stiffness'	Carrie Kibler (b) (4)	10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '800'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'mg (mg)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'once (ONCE)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '9 Nov 2020'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '0'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '9 Nov 2020'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User entered empty.	System	10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User entered empty.	System	10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:46
User entered empty.	System	10 Nov 2020 18:19:30

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 15:38:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 15:38:53
Data point term sent to Coder	System	15 Dec 2020 15:17:34
User entered 'ALKA-SELTZER COLD AND FLU (ACETAMINOPHEN 250 MG,CHLORPHENIRAMINE MALEATE 2MG, DEXTROMETHORPHAN HYDROBROMIDE 10 MG)'	Thea Marie Cordero (b) (4)	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Thea Marie Cordero (b) (4)	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'VIRAL UPPER RESPIRATORY SYMPTOMS'	Thea Marie Cordero (b) (4)	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '500/4/20' reason for change: New Information	Thea Marie Cordero (b) (4)	15 Dec 2020 15:17:23
User entered '250/2/10'	Thea Marie Cordero (b) (4)	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'mg (mg)'	Thea Marie Cordero (b) (4)	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Thea Marie Cordero (b) (4)	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'once daily (QD)'	Thea Marie Cordero (b) (4)	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Thea Marie Cordero (b) (4)	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'Oral (ORAL)'	Thea Marie Cordero (b) (4)	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered empty.	Thea Marie Cordero (b) (4)	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '5 Dec 2020'	Thea Marie Cordero (b) (4)	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '0'	Thea Marie Cordero (b) (4)	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Thea Marie Cordero (b) (4)	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '7 Dec 2020'	Thea Marie Cordero (b) (4)	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)'	Thea Marie Cordero (b) (4)	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User entered '1'	System	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User entered '1'	System	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:40
User entered '804 (804)'	System	15 Dec 2020 15:16:36

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 07:36:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 07:36:47
Data point term sent to Coder	System	12 Apr 2021 21:41:30
User entered 'ASPIRIN'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'NEUROLOGIC ISSUE DUE TO ACUTE KIDNEY INJURY'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '325'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'mg (mg)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'once (ONCE)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Oral (ORAL)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '11 Mar 2021'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '11 Mar 2021'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User entered empty.	System	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User entered empty.	System	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:37
User entered empty.	System	12 Apr 2021 21:41:15

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:02:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:02:17
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 07:51:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 07:51:16
Data point term sent to Coder	System	12 Apr 2021 21:44:40
User entered 'NORMAL SALINE SOLUTION'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'ACUTE KIDNEY INJURY'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '1000'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'mL (mL)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'once (ONCE)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '11 Mar 2021'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '11 Mar 2021'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User entered empty.	System	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User entered empty.	System	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:32
User entered empty.	System	12 Apr 2021 21:44:08

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 14:48:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 14:48:57
Data point term sent to Coder	System	12 Apr 2021 21:48:48
User entered 'LORAZEPAM'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'MRI'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '1'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'mg (mg)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'once (ONCE)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '11 Mar 2021'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '11 Mar 2021'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User entered empty.	System	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User entered empty.	System	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:28
User entered empty.	System	12 Apr 2021 21:48:00

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Apr 2021 22:20:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Apr 2021 22:20:16
Data point term sent to Coder	System	12 Apr 2021 21:54:54
User entered 'NITROFURANTOIN'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'URINARY TRACT INFECTION'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '100'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'mg (mg)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'twice daily (BID)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Oral (ORAL)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '16 Mar 2021'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '0'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '25 Mar 2021'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'No (N)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User entered '2'	System	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User entered '1'	System	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:06:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:25
User entered '804 (804)'	System	12 Apr 2021 21:54:53

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:06:10

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	22 Mar 2021 16:29:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	06 Oct 2020 20:33:57
User entered 'No (N)'	Carrie Kibler (b) (4)	14 Aug 2020 17:57:17

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:06:10

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
	(b) (4)	
User entered '11 Mar 2021'	Thea Marie Cordero	12 Apr 2021 21:49:40
	(b) (4)	

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:06:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
	(b) (4)	
User entered 'CT SCAN OF BRAIN'	Thea Marie Cordero	12 Apr 2021 21:49:40
	(b) (4)	

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
	(b) (4)	
User entered 'Adverse Event (AE)'	Thea Marie Cordero	12 Apr 2021 21:49:40
	(b) (4)	

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:06:10

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
	(b) (4)	
User entered empty.	Thea Marie Cordero	12 Apr 2021 21:49:40
	(b) (4)	

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:06:10

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '11 Mar 2021'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:50:10

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:06:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'MRI OF BRAIN'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:50:10

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Adverse Event (AE)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:50:10

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:06:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:50:10

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:06:10

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:41
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '11 Mar 2021'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:50:45

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:06:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:41
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'CHEST XRAY'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:50:45

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:41
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Adverse Event (AE)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:50:45

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:06:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:41
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:50:45

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:06:10

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:48
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '11 Mar 2021'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:51:15

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:06:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:48
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'MRA HEAD AND NECK'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:51:15

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:48
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Adverse Event (AE)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:51:15

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:06:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:48
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:51:15

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:06:10

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:52
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '11 Mar 2021'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:51:39

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:06:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:52
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'EKG'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:51:39

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:52
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Adverse Event (AE)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:51:39

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:06:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:29:52
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:51:39

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:06:10

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered '12 Mar 2021'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:52:06

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:06:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'RENAL ULTRASOUND'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:52:06

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:06:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered 'Adverse Event (AE)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:52:06

US3862007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:06:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:30:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:52:06

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'USA-US121-2021-MRNA-1273-P301000005'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Yes (Y)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Death

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Yes (Y)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Thea Marie'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Cordero'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Houston'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'TX'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered '77030'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:58:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:52:47
User entered 'US'	System	15 Mar 2021 14:09:16

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 15:59:13
User entered '2'	System	23 Mar 2021 14:17:03
User entered '1'	System	15 Mar 2021 14:09:16

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'USA-US121-2021-MRNA-1273-P301000005'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Yes (Y)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Death

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Yes (Y)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Thea Marie'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Cordero'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Houston'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'TX'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered '77030'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:58:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:52:47
User entered 'US'	System	15 Mar 2021 14:09:16

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 15:59:13
User entered '2'	System	23 Mar 2021 14:17:03
User entered '1'	System	15 Mar 2021 14:09:16

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:06:10

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
User entered '15/Mar/2021 10:09'	System	15 Mar 2021 14:09:16

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:06:10

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)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:58:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:52:47
User entered '1'	(b) (4), (b) (6)	15 Mar 2021 14:09:16

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'USA-US121-2021-MRNA-1273-P301000005'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Yes (Y)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Death

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Yes (Y)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Thea Marie'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Cordero'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Houston'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'TX'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered '77030'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:58:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:52:47
User entered 'US'	System	15 Mar 2021 14:09:16

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 15:59:13
User entered '2'	System	23 Mar 2021 14:17:03
User entered '1'	System	15 Mar 2021 14:09:16

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:06:10

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:55:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '23/Mar/2021 07:17'	System	23 Mar 2021 14:17:03

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:06:10

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)	15 Apr 2021 19:55:38
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:58:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
User entered '1'	(b) (4), (b) (6)	23 Mar 2021 14:17:03

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'USA-US121-2021-MRNA-1273-P301000005'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Yes (Y)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Death

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Yes (Y)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'No (N)'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Thea Marie'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Cordero'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'Houston'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered 'TX'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:52:47
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:09:07
User entered '77030'	System	15 Mar 2021 14:08:18

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:58:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:03:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:52:47
User entered 'US'	System	15 Mar 2021 14:09:16

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Apr 2021 15:59:13
User entered '2'	System	23 Mar 2021 14:17:03
User entered '1'	System	15 Mar 2021 14:09:16

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:06:10

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:55:46
User entered '13/Apr/2021 11:59'	System	13 Apr 2021 15:59:13

US3862007

Folder: SAE USA-US121-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:06:10

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.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:55:48
User entered '1'	(b) (4), (b) (6)	13 Apr 2021 15:59:13