

US3682001 (Prod: UCLA Vine Street Clinic - (CRS))

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:18:08

All time stamps listed in this document are displayed in GMT

US3682001

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 17:57:32

Generated On: 10 Jun 2021 09:18:08

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Participant ID

US3682001

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

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US3682001

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 23:09:15

Generated On: 10 Jun 2021 09:18:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 23:09:14

Generated On: 10 Jun 2021 09:18:08

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	58
Age Units	YEARS
Age (Derived)	58
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 23:09:14

Generated On: 10 Jun 2021 09:18:08

Date of Informed Consent ( <i>dd MMM yyyy</i> )	21 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 23:09:14

Generated On: 10 Jun 2021 09:18:08

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 23:09:15

Generated On: 10 Jun 2021 09:18:08

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 23:09:15

Generated On: 10 Jun 2021 09:18:08

Condition	ASTHMA, MODERATE,
Start date (dd MMM yyyy)	01 APR 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 23:09:15

Generated On: 10 Jun 2021 09:18:08

Condition	DVT - DEEP VENOUS THROMBOSIS
Start date (dd MMM yyyy)	UN DEC 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAR 2015
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2014
Start Year (derived)	2014
Stop Month and Year (derived)	MAR 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 23:09:15

Generated On: 10 Jun 2021 09:18:08

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 23:09:15

Generated On: 10 Jun 2021 09:18:08

Condition	L OVARIAN CYST, REMOVED, BENIGN
Start date (dd MMM yyyy)	UN APR 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 APR 2009
Stop date completely unknown	False
Start Month and Year (derived)	APR 2009
Start Year (derived)	2009
Stop Month and Year (derived)	APR 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 23:09:15

Generated On: 10 Jun 2021 09:18:08

Condition	L ANKLE FRACTURE
Start date (dd MMM yyyy)	UN OCT 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN NOV 2014
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2014
Start Year (derived)	2014
Stop Month and Year (derived)	NOV 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 23:09:15

Generated On: 10 Jun 2021 09:18:08

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 23:09:15

Generated On: 10 Jun 2021 09:18:08

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 23:09:15

Generated On: 10 Jun 2021 09:18:08

Condition	BREAST AUGMENTATION SURGERY
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 23:09:15

Generated On: 10 Jun 2021 09:18:08

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 23:09:15

Generated On: 10 Jun 2021 09:18:08

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 23:09:15

Generated On: 10 Jun 2021 09:18:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	21 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	10:45 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 10:45
Height ( <i>xxx.x</i> )	157 cm
Weight ( <i>xxx.x</i> )	192 lb
BMI ( <i>xxx.x</i> )	35.40619 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 23:09:15

Generated On: 10 Jun 2021 09:18:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 23:09:14

Generated On: 10 Jun 2021 09:18:08

Date of assessment (*dd MMM yyyy*) 21 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*) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) 19 JAN 2014

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 23:09:15

Generated On: 10 Jun 2021 09:18:08

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**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 ☒

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**Specify**

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**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 23:09:15

Generated On: 10 Jun 2021 09:18:08

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:55:12

Generated On: 10 Jun 2021 09:18:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 18:55:12

Generated On: 10 Jun 2021 09:18:08

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 144665

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 18:55:12

Generated On: 10 Jun 2021 09:18:08

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:55:12

Generated On: 10 Jun 2021 09:18:08

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 10:45
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:55:12

Generated On: 10 Jun 2021 09:18:08

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	12:36 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 12:36
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:55:12

Generated On: 10 Jun 2021 09:18:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:55:12

Generated On: 10 Jun 2021 09:18:08

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) 21 AUG 2020

What was the treatment time? (00:00-23:59) 12:06 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 12:06

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:55:12

Generated On: 10 Jun 2021 09:18:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 AUG 2020

Collection time (00:00-23:59)

11:40 (24 HR)

Collection date and time (derived)

21 AUG 2020 11:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:55:12

Generated On: 10 Jun 2021 09:18:08

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:43	21 AUG 2020 11:43
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:55:12

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

**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

98.0 °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

21 AUG 2020 12:51

PC Open Date & Time

21 AUG 2020 12:26

PC Close Date & Time

21 AUG 2020 14:56

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

**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

98.4 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	22 AUG 2020 11:09
PC Open Date & Time	21 AUG 2020 15:51
PC Close Date & Time	22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 08:15

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 07:57

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 08:55

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 08:12

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

27 AUG 2020 08:30

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 09:22

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59



US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

**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

21 AUG 2020 12:52

PC Open Date & Time

21 AUG 2020 12:26

PC Close Date & Time

21 AUG 2020 14:56

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 11:09

PC Open Date & Time

21 AUG 2020 15:51

PC Close Date & Time

22 AUG 2020 11:59

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 08:16

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 07:57

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 08:55

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 08:12

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 08:30

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 09:23

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59



US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

**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 ☐

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 12:52
PC Open Date & Time	21 AUG 2020 12:26
PC Close Date & Time	21 AUG 2020 14:56

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

**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 ☐

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 11:10
PC Open Date & Time	21 AUG 2020 15:51
PC Close Date & Time	22 AUG 2020 11:59

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:18:08

**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 ☒

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:18:08

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 08:16
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:18:08

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 07:57
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59



US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:18:08

**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 ☒

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:18:08

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 08:55
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

58 of 2851

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:18:08

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 08:13
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

60 of 2851

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:18:08

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 08:31
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

62 of 2851

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:18:08

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 09:23
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59



US3682001

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:09:14

Generated On: 10 Jun 2021 09:18:08

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3682001

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:09:14

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682001

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:09:14

Generated On: 10 Jun 2021 09:18:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682001

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:09:14

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682001

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:09:14

Generated On: 10 Jun 2021 09:18:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682001

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:09:14

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682001

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:55:13

Generated On: 10 Jun 2021 09:18:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:55:13

Generated On: 10 Jun 2021 09:18:08

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	09:12 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 09:12
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG



US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:55:13

Generated On: 10 Jun 2021 09:18:08

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	10:54 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 10:54
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	49 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3682001

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:55:13

Generated On: 10 Jun 2021 09:18:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3682001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:55:13

Generated On: 10 Jun 2021 09:18:08

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 10:21 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 10:21

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

US3682001

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:55:13

Generated On: 10 Jun 2021 09:18:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 SEP 2020
Collection time (00:00-23:59)	10:13 (24 HR)
Collection date and time (derived)	18 SEP 2020 10:13

US3682001

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:55:13

Generated On: 10 Jun 2021 09:18:08

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:16	18 SEP 2020 10:16
Nasopharyngeal Swab 2	No		

US3682001

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:55:13

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

**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

18 SEP 2020 10:59

PC Open Date & Time

18 SEP 2020 10:41

PC Close Date & Time

18 SEP 2020 13:11

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.3 °F

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

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

PC Time Stamp	18 SEP 2020 20:41
PC Open Date & Time	18 SEP 2020 14:06
PC Close Date & Time	19 SEP 2020 11:59



US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 23:00

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 20:10

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

21 SEP 2020 21:12

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 22:33

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:18:08

**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.

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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

23 SEP 2020 22:33

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 21:52

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 10:59

PC Open Date & Time

18 SEP 2020 10:41

PC Close Date & Time

18 SEP 2020 13:11

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 20:41

PC Open Date & Time

18 SEP 2020 14:06

PC Close Date & Time

19 SEP 2020 11:59



US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 23:00

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 20:11

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 21:13

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 22:33

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 22:34

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 21:53

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

**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 ☐

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 11:00
PC Open Date & Time	18 SEP 2020 10:41
PC Close Date & Time	18 SEP 2020 13:11



US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

**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 ☐

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 20:42
PC Open Date & Time	18 SEP 2020 14:06
PC Close Date & Time	19 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:18:08

**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 ☒

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:18:08

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 23:01
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:18:08

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 ☒

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:18:08

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

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:18:08

**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 ☒

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:18:08

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 21:13
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59



US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:18:08

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 ☒

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:18:08

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 22:33
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:18:08

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 ☒

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:18:08

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 22:34
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:18:08

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 21:53
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp 25 SEP 2020 21:28

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp 26 SEP 2020 22:25

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59



US3682001

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:18:08

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 SEP 2020 21:28
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3682001

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:18:08

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 SEP 2020 22:25
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3682001

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:09:14

Generated On: 10 Jun 2021 09:18:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682001

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:09:14

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682001

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:55:12

Generated On: 10 Jun 2021 09:18:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682001

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:55:12

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682001

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:55:12

Generated On: 10 Jun 2021 09:18:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682001

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:55:12

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3682001

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:55:13

Generated On: 10 Jun 2021 09:18:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3682001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:55:13

Generated On: 10 Jun 2021 09:18:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	16 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	09:23 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 09:23
Temperature ( <i>xxx.x</i> )	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	72 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682001

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:55:13

Generated On: 10 Jun 2021 09:18:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3682001

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:55:13

Generated On: 10 Jun 2021 09:18:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 OCT 2020

Collection time (00:00-23:59)

10:15 (24 HR)

Collection date and time (derived)

16 OCT 2020 10:15

US3682001

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:55:13

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 OCT 2020 09:48:48
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3682001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 08:28:15

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3682001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 16:06:50

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59



US3682001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

<b>TIMEPOINT</b>	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 22:51:54
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 12:00:57
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 DEC 2020 12:39:37
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	07 DEC 2020 10:13:43
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 14:36:43
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	22 DEC 2020 12:08:17
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59



US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	29 DEC 2020 08:07:46
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

<b>TIMEPOINT</b>	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	04 JAN 2021 07:57:06
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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	11 JAN 2021 12:00:43
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**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

18 JAN 2021 14:29:21

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 12:32:14

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 11:12:46

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	07 FEB 2021 10:01:23
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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	16 FEB 2021 09:37:47
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59



US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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 <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	22 FEB 2021 20:54:20
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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	01 MAR 2021 11:01:23
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 10:18:14

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 11:06:55

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 12:11:32

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**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

30 MAR 2021 12:04:17

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 10:16:12

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 08:13:05

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59



US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**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

19 APR 2021 10:46:17

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 11:48:56

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 12:46:37

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**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 ☐

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 JUN 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUN 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUN 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 JUL 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 JUL 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUL 2021 23:59
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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**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 ☐



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 AUG 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**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 ☐

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 SEP 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 SEP 2021 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 SEP 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 SEP 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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17 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 OCT 2021 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59
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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59
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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 DEC 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**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 ☐

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 FEB 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 FEB 2022 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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27 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**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 ☐

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 MAR 2022 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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03 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 APR 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 APR 2022 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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17 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 MAY 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 JUN 2022 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JUN 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JUN 2022 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2022 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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17 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JUL 2022 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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14 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 AUG 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 SEP 2022 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

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25 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 SEP 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**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 ☐

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

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[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

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US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

**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 ☐



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

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

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2022 23:59

US3682001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:18:08

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3682001

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:18:08

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 11:01:33

US3682001

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:08:20

Generated On: 10 Jun 2021 09:18:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682001

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:08:20

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3682001

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682001

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682001

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682001

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682001

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682001

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682001

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3682001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 20:35:35

Generated On: 10 Jun 2021 09:18:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	5 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	09:07 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 09:07
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> )	64 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3682001

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 MAR 2021

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

US3682001

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 20:35:35

Generated On: 10 Jun 2021 09:18:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 MAR 2021
Collection time (00:00-23:59)	09:24 (24 HR)
Collection date and time (derived)	5 MAR 2021 09:24

US3682001

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682001

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 22:48:16

Generated On: 10 Jun 2021 09:18:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682001

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 22:48:16

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3682001**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

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*

**US3682001**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3682001**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:18:08**

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"/>



**US3682001**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 09:18:08**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3682001

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3682001

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

Form: Unblinding

Data signed: (b) (4) 01 Apr 2021 20:35:35

Generated On: 10 Jun 2021 09:18:08

Date of updated informed consent ( <i>dd MMM yyyy</i> )	8 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	8 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

**US3682001**

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

**Form: Vital Signs - Dosing**

**Data signed:** (b) (4) 05 Mar 2021 23:19:17

**Generated On: 10 Jun 2021 09:18:08**

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

US3682001

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 JAN 2021
Time of assessment (00:00-23:59)	10:26 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 10:26
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3682001

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 JAN 2021
Time of assessment (00:00-23:59)	11:46 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 11:46
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3682001

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

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 JAN 2021

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

US3682001

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

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 8 JAN 2021

What was the treatment time? (00:00-23:59) 11:14 (24 HR)

Treatment Date and Time (derived) 8 JAN 2021 11:14

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



US3682001

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 JAN 2021
Collection time (00:00-23:59)	10:36 (24 HR)
Collection date and time (derived)	08 JAN 2021 10:36

US3682001

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 JAN 2021
Collection time (00:00 - 23:59)	10:40
Collection Date and Time (derived)	08 JAN 2021 10:40

US3682001

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

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682001

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:08:20

Generated On: 10 Jun 2021 09:18:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682001

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:08:20

Generated On: 10 Jun 2021 09:18:08

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

US3682001

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 FEB 2021
Time of assessment (00:00-23:59)	09:15 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 09:15
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 FEB 2021
Time of assessment (00:00-23:59)	10:09 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 10:09
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG



US3682001

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 17:57:33

Generated On: 10 Jun 2021 09:18:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 FEB 2021

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

US3682001

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 17:57:33

Generated On: 10 Jun 2021 09:18:08

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 5 FEB 2021

What was the treatment time? (00:00-23:59) 09:38 (24 HR)

Treatment Date and Time (derived) 5 FEB 2021 09:38

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

US3682001

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:57:33

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682001

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682001

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682001

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3682001

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	5 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	9:07 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 9:07
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> )	64 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682001

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 MAR 2021

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



US3682001

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 MAR 2021

Collection time (00:00-23:59)

09:24 (24 HR)

Collection date and time (derived)

05 MAR 2021 09:24

US3682001

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 17:57:32

Generated On: 10 Jun 2021 09:18:08

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3682001

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Feb 2021 17:57:32

Generated On: 10 Jun 2021 09:18:08

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

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US3682001

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Feb 2021 17:57:32

Generated On: 10 Jun 2021 09:18:08

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

US3682001

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Feb 2021 17:57:32

Generated On: 10 Jun 2021 09:18:08

AEID

Adverse event

LYMPHADENOPATHY -  
CERVICAL - BILATERAL

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)

3 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

4 OCT 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 ☐

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US3682001

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Feb 2021 17:57:32

Generated On: 10 Jun 2021 09:18:08

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3682001

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Feb 2021 17:57:32

Generated On: 10 Jun 2021 09:18:08

AEID	
Adverse event	NUMBNESS IN L ARM
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)	16 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 OCT 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	

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Folder: Adverse Events

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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 True

Concomitant Medication False

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 PT REPORTS NUMBNESS IN HER  
L ARM DURING SLEEP  
STARTING AROUND 3:00 AM,  
RESOLVED WITHOUT  
SEQUELAE BY 7:00.

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)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Feb 2021 17:57:32

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AEID	USA-US081-2020-MRNA-1273-P30 1000002
Adverse event	WORSENING OF OSTEOARTHRITIS R KNEE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 SEP 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)	30 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	30 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	01 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Form: Adverse Events (4)

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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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PT HAD A TOTAL R KNEE REPLACEMENT. THIS WAS A PLANNED SURGERY. PT'S MEDICAL RECORDS TO BE REQUESTED.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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**Folder: Adverse Events**

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

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0

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Feb 2021 17:57:32

Generated On: 10 Jun 2021 09:18:08

AEID

Adverse event

PAIN RELATED TO RIGHT  
TOTAL KNEE ARTHROPLASTY

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)

1 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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 ☐

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Form: Adverse Events (5)

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 12 Feb 2021 17:57:32

Generated On: 10 Jun 2021 09:18:08

AEID

Adverse event

NAUSEA SECONDARY TO  
RIGHT TOTAL KNEE  
ARTHROPLASTY AND  
ASSOCIATED MEDICATIONS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 DEC 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 ☐

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Form: Adverse Events (6)

Data signed: (b) (4) 12 Feb 2021 17:57:32

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 12 Feb 2021 17:57:32

Generated On: 10 Jun 2021 09:18:08

AEID

Adverse event

CONSTIPATION SECONDARY  
TO RIGHT TOTAL KNEE  
ARTHROPLASTY AND  
ASSOCIATED MEDICATIONS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 DEC 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 ☐

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 12 Feb 2021 17:57:32

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 12 Feb 2021 17:57:32

Generated On: 10 Jun 2021 09:18:08

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 SEP 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)	25 SEP 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	

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Folder: Adverse Events

Form: Adverse Events (8)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 17:57:33

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

Yes ☒

No ☐

---

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

---

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

Name of Medication QVAR INHALER

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 22:48:15

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

Name of Medication XOPENEX INHALER

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA EXACERBATION

Dose per administration 45

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 22:48:15

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

Name of Medication B COMPLEX VITAMIN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

Name of Medication D3

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

Name of Medication PROBIOTIC SUPPLEMENT

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

Name of Medication COENZYME Q10

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

	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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

Name of Medication MAGNESIUM BISGLYCINATE

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

Name of Medication RED YEAST RICE

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

Name of Medication NIACIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

Name of Medication OMEGA 3 FATTY ACIDS

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 1280

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

	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) _____		
Start date completely unknown		True
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)		2
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

Name of Medication LIVER SUPPORT BLEND - NAC  
AND MILK THISTLE EXTRACT

Prophylaxis Yes ☐  
No ☒

Indication EARLY STEATOHEPATITIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

Name of Medication LIPOSOMAL GLUTATHIONE

Prophylaxis Yes ☐  
No ☒

Indication EARLY STEATOHEPATITIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

	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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		4 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

Name of Medication CALCIUM

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

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Name of Medication IMMUCORE MULTIVITAMIN  
SUPPLEMENT(VITAMIN D,  
VITAMIN C, NIACIN, ZINC,  
SELENIUM)

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 22:48:15

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Name of Medication ALEVE

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 220

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

	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)		25 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 22:48:15

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Name of Medication ASTRAGALUS

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 30

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

If dose unit is Other, specify GTTS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

	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)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

Name of Medication NAPROXEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE/LYMPHADENOPATHY, CERVICAL, BILATERAL

Dose per administration 440

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

	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)	3 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		4 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

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Name of Medication OXYCODONE

Prophylaxis Yes ☐  
No ☒

Indication PAIN RELATED TO RIGHT  
TOTAL KNEE ARTHROPLASTY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 22:48:15

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 22:48:15

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Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication PAIN RELATED TO RIGHT  
TOTAL KNEE ARTHROPLASTY

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 22:48:15

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	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)	01 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 22:48:15

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Name of Medication ACETAMINOPHEN/DIPHENHYD  
RAMINE

Prophylaxis Yes ☐  
No ☒

Indication PAIN RELATED TO RIGHT  
TOTAL KNEE ARTHROPLASTY

Dose per administration 500/25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

	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)		01 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 22:48:15

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Name of Medication DUCOLAX

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION RELATED TO  
RIGHT TOTAL KNEE  
ARTHROPLASTY AND  
ASSOCIATED MEDICATIONS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 22:48:15

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	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)		02 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

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Name of Medication APIXABAN

Prophylaxis Yes ☒  
No ☐

Indication DEEP VEIN THROMBOSIS  
PROPHYLAXIS

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 16 Apr 2021 22:48:15

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	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)	01 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	21 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 22:48:15

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Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☒  
No ☐

Indication GASTROESOPHAGEAL REFLUX  
DISEASE PROPHYLAXIS

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

	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)	01 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication PAIN AND INFLAMMATION  
SECONDARY TO RIGHT TOTAL  
KNEE ARTHROPLASTY

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

	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)		03 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication POST OP PAIN R KNEE  
REPLACEMENT

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

	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)	16 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

Name of Medication NAPROXEN

Prophylaxis Yes ☐  
No ☒

Indication PAIN RELATED TO RIGHT  
TOTAL KNEE ARTHROPLASTY

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 16 Apr 2021 22:48:15

Generated On: 10 Jun 2021 09:18:08

	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)	27 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3682001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 17:57:33

Generated On: 10 Jun 2021 09:18:08

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3682001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Feb 2021 17:57:33

Generated On: 10 Jun 2021 09:18:08

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
30 NOV 2020	TOTAL RIGHT KNEE REPLACEMENT	Adverse Event	

US3682001

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:18:08

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

US3682001

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:18:08

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 ☐

US3682001

Folder: SAE USA-US081-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

SAEID	USA-US081-2020-MRNA-1273-P301000002
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3682001

Folder: SAE USA-US081-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

SAEID	USA-US081-2020-MRNA-1273-P301000002
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	03/DEC/2020 08:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3682001

Folder: SAE USA-US081-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

SAEID	USA-US081-2020-MRNA-1273-P301000002
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	10/DEC/2020 09:51
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

US3682001

Folder: SAE USA-US081-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

SAEID	USA-US081-2020-MRNA-1273-P301000002
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/DEC/2020 13:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3682001

Folder: SAE USA-US081-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

SAEID	USA-US081-2020-MRNA-1273-P301000002
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	30/DEC/2020 09:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3682001

Folder: SAE USA-US081-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 05 Mar 2021 23:19:17

Generated On: 10 Jun 2021 09:18:08

SAEID	USA-US081-2020-MRNA-1273-P301000002
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	JESSE
Investigator's Last Name	CLARK
Site Address: Street	
Site Address: City	
Site Address: State	CA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	14/JAN/2021 09:26
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

US3682001 (Prod: UCLA Vine Street Clinic - (CRS))

**US3682001**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:18:08**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'US3682001'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 16:54:51

US3682001

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:18:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Timothy Hall (b) (4)	21 Aug 2020 17:27:41

**US3682001**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 16:54:51



**US3682001**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Clinic (Clinic)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:27:41

**US3682001**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'SCRN'	System	21 Aug 2020 17:27:41

US3682001

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:18:08

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered (b) (6) 1962'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 16:54:52

**US3682001**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:18:08**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '58'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:29:00

**US3682001**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:18:08**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'YEARS'	System	21 Aug 2020 17:29:00

**US3682001**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:18:08**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '58'	System	21 Aug 2020 17:29:30

**US3682001**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:18:08**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Female (F)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:29:00

**US3682001**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:18:08**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Timothy Hall (b) (4)	21 Aug 2020 17:29:00



**US3682001**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:18:08**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'I'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:29:00

**US3682001**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:18:08**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:29:00

**US3682001**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:18:08**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:29:00

**US3682001**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:18:08**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:29:00

**US3682001**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:18:08**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:29:00

**US3682001**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:18:08**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:29:00

**US3682001**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:18:08**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:29:00

**US3682001**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:18:08**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:29:00



**US3682001**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:18:08**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:29:00

US3682001

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:08

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '21 Aug 2020'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:29:30

**US3682001**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'Aug 2020'	System	21 Aug 2020 17:29:30

**US3682001**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '2020'	System	21 Aug 2020 17:29:30

**US3682001**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:18:08**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Amendment 2 (2)' reason for change:	(b) (4)	
Data Entry Error	Jesse Clark (b) (4)	21 Aug 2020 21:56:45
User entered 'Amendment 5 (5)'	(b) (4)	
	Timothy Hall (b) (4)	21 Aug 2020 17:29:30
	(b) (4)	

**US3682001**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:29:30

**US3682001**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:29:30

**US3682001**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:18:08**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:29:30



US3682001

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:18:08

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:29:30

**US3682001**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:18:08**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 16:54:51

**US3682001**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:18:08**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'I'	System	21 Aug 2020 17:29:30

**US3682001**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Timothy Hall (b) (4)	21 Aug 2020 17:27:08

**US3682001**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:18:08**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:29:57

US3682001

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:18:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User closed query 'Per MM: Please retain 'MODERATE ASTHMA' and move medication 'QVAR' to CM listings. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 12:04:02
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 23:04:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 23:04:46
Data point term sent to Coder	System	22 Sep 2020 20:55:29
Query 'Per MM: Please retain 'MODERATE ASTHMA' and move medication 'QVAR' to CM listings.	Susan Reed (b) (4) (b) (4)	22 Sep 2020 20:55:10
' answered with 'data corrected' (Site from DM).		
Coding entries removed.	Susan Reed (b) (4) (b) (4)	22 Sep 2020 20:55:02
User entered 'ASTHMA, MODERATE,' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	22 Sep 2020 20:55:02
User opened query 'Per MM: Please retain 'MODERATE ASTHMA' and move medication 'QVAR' to CM listings. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 13:46:16
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Drug-induced asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:35:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:35:46
Data point term sent to Coder	System	21 Aug 2020 17:36:40
User entered 'asthma, moderate, on Qvar BID. no hx of hospitalization for asthma.'	Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:35:58

**US3682001**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '01 Apr 2010'	(b) (4) Timothy Hall (b) (4)	21 Aug 2020 17:35:58

**US3682001**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:35:58



**US3682001**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:35:58

**US3682001**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:35:58

**US3682001**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:35:58

**US3682001**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'Apr 2010'	System	21 Aug 2020 17:35:58

**US3682001**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '2010'	System	21 Aug 2020 17:35:58

**US3682001**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered empty.	System	21 Aug 2020 17:35:58

**US3682001**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered empty.	System	21 Aug 2020 17:35:58

US3682001

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:18:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User closed query ""Per MM: Please split and record separately: 1. DVT 2. Left Ankle Fracture." ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 08:32:10
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: DVT - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 23:51:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 23:51:47
Query ""Per MM: Please split and record separately: 1. DVT 2. Left Ankle Fracture." ' answered with 'L ankle fracture already recorded separately' (Site from DM).	Timothy Hall (b) (4) (b) (4)	22 Sep 2020 21:08:13
Data point term sent to Coder	System	22 Sep 2020 21:07:42
Coding entries removed.	Timothy Hall (b) (4) (b) (4)	22 Sep 2020 21:07:15
User entered 'DVT - deep venous thrombosis' reason for change: Per Query Resolution	Timothy Hall (b) (4) (b) (4)	22 Sep 2020 21:07:15
User opened query ""Per MM: Please split and record separately: 1. DVT 2. Left Ankle Fracture." ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 13:48:14
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis leg - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:19:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:19:35
Data point term sent to Coder	System	21 Aug 2020 17:37:42
User entered 'DVT in 2014 following L ankle fracture'	Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:37:28



**US3682001**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'UN Dec 2014'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:37:28

**US3682001**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:37:28

**US3682001**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:37:28

**US3682001**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'UN Mar 2015'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:37:28

**US3682001**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:37:28

**US3682001**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'Dec 2014'	System	21 Aug 2020 17:37:28

**US3682001**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '2014'	System	21 Aug 2020 17:37:28

**US3682001**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'Mar 2015'	System	21 Aug 2020 17:37:28



**US3682001**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '2015'	System	21 Aug 2020 17:37:28

US3682001

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:18:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatocellular damage and hepatitis NEC, PT: Steatohepatitis, LLT: Steatohepatitis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 00:03:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 00:03:43
Data point term sent to Coder	System	21 Aug 2020 17:38:45
User entered 'early steatohepatitis. controlled with diet'	Timothy Hall (b) (4)	21 Aug 2020 17:38:11

**US3682001**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'un UNK 2012'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:38:11

**US3682001**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:38:11

**US3682001**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Timothy Hall (b) (4)	21 Aug 2020 17:38:11

**US3682001**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	(b) (4) Timothy Hall (b) (4)	21 Aug 2020 17:38:11

**US3682001**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4)	21 Aug 2020 17:38:11

**US3682001**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'Jan 2012'	System	21 Aug 2020 17:38:11



**US3682001**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '2012'	System	21 Aug 2020 17:38:11

**US3682001**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered empty.	System	21 Aug 2020 17:38:11

**US3682001**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered empty.	System	21 Aug 2020 17:38:11

US3682001

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:18:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Ovarian therapeutic procedures, PT: Ovarian cystectomy, LLT: Ovarian cystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 06:57:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 06:57:20
User closed query 'Per DM CLR: Please update the condition to confirm if the OVARIAN CYST was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	08 Oct 2020 19:09:34
' (Site from DM).		
Query 'Per DM CLR: Please update the condition to confirm if the OVARIAN CYST was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	08 Oct 2020 16:59:58
' answered with 'Update complete' (Site from DM).		
Data point term sent to Coder	System	08 Oct 2020 16:59:58
Coding entries removed.	(b) (4), (b) (6)	08 Oct 2020 16:59:50
User entered 'L OVARIAN CYST, REMOVED, BENIGN' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Oct 2020 16:59:50
User opened query 'Per DM CLR: Please update the condition to confirm if the OVARIAN CYST was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	05 Oct 2020 16:51:38
' (Site from DM).		
User closed query 'Per MM: please review and update the term to final diagnosis	(b) (4), (b) (6)	24 Sep 2020 08:32:26
' (Site from DM).		

US3682001

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:18:08

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Ovarian therapeutic procedures, PT: Ovarian cystectomy, LLT: Ovarian cystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 23:49:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 23:49:46
Data point term sent to Coder	System	22 Sep 2020 21:09:43
Query 'Per MM: please review and update the term to final diagnosis	Timothy Hall (b) (4)	22 Sep 2020 21:09:25
' answered with 'done' (Site from DM).	(b) (4)	
Coding entries removed.	Timothy Hall (b) (4)	22 Sep 2020 21:09:20
User entered 'L OVARIAN CYST, REMOVED'	(b) (4)	
reason for change: Per Query Resolution	Timothy Hall (b) (4)	22 Sep 2020 21:09:20
User opened query 'Per MM: please review and update the term to final diagnosis	(b) (4), (b) (6)	22 Sep 2020 13:49:21
' (Site from DM).		
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Ovarian therapeutic procedures, PT: Ovarian cystectomy, LLT: Ovarian cystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:16:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 18:16:49
Data point term sent to Coder	System	21 Aug 2020 18:17:29
User entered 'L ovarian cyst, removed while preserving most of ovary.'	Timothy Hall (b) (4)	21 Aug 2020 18:17:25
	(b) (4)	

**US3682001**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'UN Apr 2009'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:17:25

**US3682001**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:17:25

**US3682001**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:17:25



**US3682001**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'UN Apr 2009'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:17:25

**US3682001**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:17:25

**US3682001**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'Apr 2009'	System	21 Aug 2020 18:17:25

**US3682001**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '2009'	System	21 Aug 2020 18:17:25

**US3682001**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'Apr 2009'	System	21 Aug 2020 18:17:25

**US3682001**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '2009'	System	21 Aug 2020 18:17:25

US3682001

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:18:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Ankle fracture - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 08:32:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 08:32:17
Data point term sent to Coder	System	21 Aug 2020 18:18:32
User entered 'L ankle fracture'	Timothy Hall (b) (4)	21 Aug 2020 18:18:06

**US3682001**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'UN Oct 2014'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:18:06



**US3682001**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:18:06

**US3682001**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:18:06

**US3682001**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'UN Nov 2014'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:18:06

**US3682001**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:18:06

**US3682001**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'Oct 2014'	System	21 Aug 2020 18:18:06

**US3682001**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '2014'	System	21 Aug 2020 18:18:06

**US3682001**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'Nov 2014'	System	21 Aug 2020 18:18:06

**US3682001**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '2014'	System	21 Aug 2020 18:18:06



US3682001

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:18:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
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)	21 Aug 2020 18:19:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:19:23
Data point term sent to Coder	System	21 Aug 2020 18:18:32
User entered 'osteoarthritis'	Timothy Hall (b) (4)	21 Aug 2020 18:18:23

**US3682001**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'UN UNK 2015'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:18:23

**US3682001**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:18:23

**US3682001**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:18:23

**US3682001**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	(b) (4) Timothy Hall (b) (4)	21 Aug 2020 18:18:23

**US3682001**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:18:23

**US3682001**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'Jan 2015'	System	21 Aug 2020 18:18:23

**US3682001**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '2015'	System	21 Aug 2020 18:18:23



**US3682001**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered empty.	System	21 Aug 2020 18:18:23

**US3682001**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered empty.	System	21 Aug 2020 18:18:23

US3682001

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:18:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User closed query 'Per MM: Please retain 'ALLERGIC TO SULFA DRUGS' and remove the remaining terms ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 08:32:40
User coded data point as SOC: Immune system disorders, HLT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:11:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:11:43
Data point term sent to Coder	System	22 Sep 2020 21:10:46
Query 'Per MM: Please retain 'ALLERGIC TO SULFA DRUGS' and remove the remaining terms ' answered with 'done' (Site from DM).	Timothy Hall (b) (4) (b) (4)	22 Sep 2020 21:10:00
Coding entries removed.	Timothy Hall (b) (4) (b) (4)	22 Sep 2020 21:09:51
User entered 'ALLERGIC TO SULFA DRUGS' reason for change: Data Entry Error	Timothy Hall (b) (4) (b) (4)	22 Sep 2020 21:09:51
User opened query 'Per MM: Please retain 'ALLERGIC TO SULFA DRUGS' and remove the remaining terms ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 13:50:22
User coded data point as SOC: Immune system disorders, HLT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 04:38:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 04:38:45
Data point term sent to Coder	System	21 Aug 2020 18:19:33
User entered 'allergic to sulfa drugs. first noted in 2010. no repeat exposures to sulfa'	Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:19:01

**US3682001**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'UN UNK 2010'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:19:01

**US3682001**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:19:01

**US3682001**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:19:01

**US3682001**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	(b) (4) Timothy Hall (b) (4)	21 Aug 2020 18:19:01

**US3682001**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:19:01



**US3682001**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'Jan 2010'	System	21 Aug 2020 18:19:01

**US3682001**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '2010'	System	21 Aug 2020 18:19:01

**US3682001**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered empty.	System	21 Aug 2020 18:19:01

**US3682001**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered empty.	System	21 Aug 2020 18:19:01

US3682001

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:18:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Augmentation mammoplasty - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 06:11:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 06:11:24
Data point term sent to Coder	System	21 Aug 2020 18:21:39
User entered 'breast augmentation surgery'	Timothy Hall (b) (4)	21 Aug 2020 18:20:49

**US3682001**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'UN UNK 2002'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:20:49

**US3682001**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:20:49

US3682001

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:18:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 07:08:27
' (Site from DM).		
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.	Susan Reed (b) (4)	06 Oct 2020 23:51:11
' answered with 'updated form' (Site from DM).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Susan Reed (b) (4)	06 Oct 2020 23:51:01
	(b) (4)	
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.	(b) (4), (b) (6)	05 Oct 2020 16:53:38
' (Site from DM).		
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 18:20:49
	(b) (4)	



**US3682001**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'un UNK 2002' reason for change:	(b) (4)	
Data Entry Error	Susan Reed (b) (4)	06 Oct 2020 23:51:01
User entered empty.	(b) (4)	
	Timothy Hall (b) (4)	21 Aug 2020 18:20:49
	(b) (4)	

**US3682001**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:20:49

**US3682001**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'Jan 2002'	System	21 Aug 2020 18:20:49

**US3682001**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '2002'	System	21 Aug 2020 18:20:49

**US3682001**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'Jan 2002'	System	06 Oct 2020 23:51:01
User entered empty.	System	21 Aug 2020 18:20:49

**US3682001**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '2002'	System	06 Oct 2020 23:51:01
User entered empty.	System	21 Aug 2020 18:20:49

US3682001

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:18:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
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)	09 Oct 2020 00:01:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 00:01:28
Data point term sent to Coder	System	08 Oct 2020 19:28:15
User entered 'HYPERLIPIDEMIA'	(b) (4), (b) (6)	08 Oct 2020 19:27:48

**US3682001**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:27:48



**US3682001**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:27:48

**US3682001**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:18:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:27:48

**US3682001**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:27:48

**US3682001**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:18:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:27:48

**US3682001**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered empty.	System	08 Oct 2020 19:27:48

**US3682001**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered empty.	System	08 Oct 2020 19:27:48

**US3682001**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered empty.	System	08 Oct 2020 19:27:48

**US3682001**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered empty.	System	08 Oct 2020 19:27:48



US3682001

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:18:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 17:52:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 17:52:18
Data point term sent to Coder	System	13 Oct 2020 17:51:41
User entered 'Post menopausal'	Susan Reed (b) (4)	13 Oct 2020 17:51:40

**US3682001**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'UN UNK 2019' reason for change:	(b) (4)	
Data Entry Error	Susan Reed (b) (4)	13 Oct 2020 19:48:30
User entered 'un UNK 2014'	(b) (4)	
	Susan Reed (b) (4)	13 Oct 2020 17:51:40
	(b) (4)	

**US3682001**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Susan Reed (b) (4) (b) (4)	13 Oct 2020 17:51:40

**US3682001**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:18:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	13 Oct 2020 17:51:40

**US3682001**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	13 Oct 2020 17:51:40

**US3682001**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:18:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Susan Reed (b) (4) (b) (4)	13 Oct 2020 17:51:40

**US3682001**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'Jan 2019'	System	13 Oct 2020 19:48:30
User entered 'Jan 2014'	System	13 Oct 2020 17:51:40

**US3682001**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '2019'	System	13 Oct 2020 19:48:30
User entered '2014'	System	13 Oct 2020 17:51:40



**US3682001**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered empty.	System	13 Oct 2020 17:51:40

**US3682001**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered empty.	System	13 Oct 2020 17:51:40

**US3682001**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:48:08

**US3682001**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '21 Aug 2020'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:48:08

**US3682001**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '10:45'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:48:08

**US3682001**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '21 Aug 2020 10:45'	System	21 Aug 2020 17:48:08

**US3682001**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '157' cm	(b) (4)	
	Timothy Hall (b) (4)	21 Aug 2020 17:48:08
DataPoint set to visible.	(b) (4)	
	System	21 Aug 2020 17:29:30

US3682001

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:08

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '192' lb	(b) (4) Timothy Hall (b) (4)	21 Aug 2020 17:48:08
DataPoint set to visible.	(b) (4) System	21 Aug 2020 17:29:30



**US3682001**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
Amendment Manager: User entered '35.40619'	System	17 Sep 2020 00:18:31
User entered '35.4'	System	21 Aug 2020 17:48:08
DataPoint set to visible.	System	21 Aug 2020 17:29:30

**US3682001**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'kg/m2'	System	21 Aug 2020 17:48:08
DataPoint set to visible.	System	21 Aug 2020 17:29:30

US3682001

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User closed query 'Re-query: Per CDM: Response noted, kindly consider keeping units blank as Temperature is ND.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 05:13:45
Query 'Re-query: Per CDM: Response noted, kindly consider keeping units blank as Temperature is ND.' answered with 'will do' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 16:27:06
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	10 Sep 2020 16:26:57
User opened query 'Re-query: Per CDM: Response noted, kindly consider keeping units blank as Temperature is ND.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 06:09:34
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 06:09:34
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'Screening and visit 1 done same day.' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Sep 2020 17:16:56
User entered missing code ND - Not Done; reason for change Per Query Resolution	Susan Reed (b) (4) (b) (4)	09 Sep 2020 17:16:39
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 17:10:10

US3682001

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.6' F	Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:48:08

US3682001

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty; reason for change Per Query Resolution	(b) (4) Susan Reed (b) (4)	09 Sep 2020 17:16:39
User entered 'Other (Other)'	(b) (4) Timothy Hall (b) (4)	21 Aug 2020 17:48:08

US3682001

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty; reason for change Per Query Resolution	(b) (4) Susan Reed (b) (4)	09 Sep 2020 17:16:39
User entered 'infrared'	Timothy Hall (b) (4)	21 Aug 2020 17:48:08

US3682001

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 17:17:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	09 Sep 2020 17:17:39
User entered missing code ND - Not Done; reason for change Per Query Resolution	Susan Reed (b) (4)	09 Sep 2020 17:17:39
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 17:16:39
User entered empty; reason for change Per Query Resolution	System	09 Sep 2020 17:16:39
User entered '59'	Susan Reed (b) (4)	09 Sep 2020 17:16:39
	(b) (4)	
	Timothy Hall (b) (4)	21 Aug 2020 17:48:08
	(b) (4)	

**US3682001**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'bpm'	System	09 Sep 2020 17:17:39
User entered empty.	System	09 Sep 2020 17:16:39
User entered 'bpm'	System	21 Aug 2020 17:48:08



US3682001

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 17:17:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	09 Sep 2020 17:17:39
User entered missing code ND - Not Done; reason for change Per Query Resolution	Susan Reed (b) (4)	09 Sep 2020 17:17:39
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 17:16:39
User entered empty; reason for change Per Query Resolution	System	09 Sep 2020 17:16:39
User entered '16'	Susan Reed (b) (4)	09 Sep 2020 17:16:39
	(b) (4)	
	Timothy Hall (b) (4)	21 Aug 2020 17:48:08
	(b) (4)	

**US3682001**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'breaths/min'	System	09 Sep 2020 17:17:39
User entered empty.	System	09 Sep 2020 17:16:39
User entered 'breaths/min'	System	21 Aug 2020 17:48:08

US3682001

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 17:17:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	09 Sep 2020 17:17:39
User entered missing code ND - Not Done; reason for change Per Query Resolution	Susan Reed (b) (4)	09 Sep 2020 17:17:39
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 17:16:39
User entered empty; reason for change Per Query Resolution	System	09 Sep 2020 17:16:39
User entered '149'	Susan Reed (b) (4)	09 Sep 2020 17:16:39
	(b) (4)	
	Timothy Hall (b) (4)	21 Aug 2020 17:48:08
	(b) (4)	

**US3682001**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'mmHg'	System	09 Sep 2020 17:17:39
User entered empty.	System	09 Sep 2020 17:16:39
User entered 'mmHg'	System	21 Aug 2020 17:48:08

US3682001

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 17:17:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	09 Sep 2020 17:17:39
User entered missing code ND - Not Done; reason for change Per Query Resolution	Susan Reed (b) (4)	09 Sep 2020 17:17:39
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 17:16:39
User entered empty; reason for change Per Query Resolution	System	09 Sep 2020 17:16:39
User entered '91'	Susan Reed (b) (4)	09 Sep 2020 17:16:39
	(b) (4)	
	Timothy Hall (b) (4)	21 Aug 2020 17:48:08
	(b) (4)	

**US3682001**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'mmHg'	System	09 Sep 2020 17:17:39
User entered empty.	System	09 Sep 2020 17:16:39
User entered 'mmHg'	System	21 Aug 2020 17:48:08

**US3682001**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38

**US3682001**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38



**US3682001**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:18:08**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:31:07

**US3682001**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:18:08**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '21 Aug 2020'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:31:07

**US3682001**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:18:08**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '21 Aug 2020'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:32:02

**US3682001**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:18:08**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4)	21 Aug 2020 17:32:02

US3682001

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:18:08

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:24:13
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'MH updated' (Site from DM).	Susan Reed (b) (4) (b) (4)	13 Oct 2020 17:51:54
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 00:05:20
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:32:02

**US3682001**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:18:08**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:32:02

US3682001

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:18:08

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:32:02

**US3682001**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:18:08**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:32:02



US3682001

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '19 Jan 2014'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:32:02

**US3682001**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:18:08**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:32:02

US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4)	21 Aug 2020 17:41:15

US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4)	21 Aug 2020 17:41:15



US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

**US3682001**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:18:08**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15



US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'I'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '0'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

US3682001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:18:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 17:41:15

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	21 Aug 2020 18:22:06



**US3682001**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '21 Aug 2020'	(b) (4) Simone Riley (b) (4)	21 Aug 2020 18:22:06

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Clinic (Clinic)'	(b) (4) Simone Riley (b) (4) (b) (4)	21 Aug 2020 18:22:06

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'VISIT1'	System	21 Aug 2020 18:22:06

US3682001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:24:50

US3682001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:08

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '144665'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:24:50

US3682001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:18:08

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:24:50

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:18:08**

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	21 Aug 2020 18:22:37

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:18:08**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'No (N)'	Simone Riley (b) (4)	21 Aug 2020 18:22:37



**US3682001**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:18:08**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'No (N)'	(b) (4) Simone Riley (b) (4) (b) (4)	21 Aug 2020 18:22:37

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:18:08**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'No (N)'	(b) (4) Simone Riley (b) (4) (b) (4)	21 Aug 2020 18:22:37

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:18:08**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'No (N)'	(b) (4) Simone Riley (b) (4)	21 Aug 2020 18:22:37

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:18:08**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4)	22 Sep 2020 21:05:33
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:38:22
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:03:30

US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User closed query 'Per CDM: Response noted; however, per CCGs pages 15-16, ND should be recorded for WEIGHT also. Please update accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:26:09
Query 'Per CDM: Response noted; however, per CCGs pages 15-16, ND should be recorded for WEIGHT also. Please update accordingly. Thank you.' answered with 'Screening and visit 1 done on the same day.' (Site from DM).	Susan Reed (b) (4) (b) (4)	10 Sep 2020 16:30:32
User opened query 'Per CDM: Response noted; however, per CCGs pages 15-16, ND should be recorded for WEIGHT also. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 15:32:24
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 15:32:24
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Screening and visit 1 done same day' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Sep 2020 17:18:14
User entered missing code ND - Not Done; reason for change Per Query Resolution	Susan Reed (b) (4) (b) (4)	09 Sep 2020 17:18:06
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 17:10:20
User entered empty.	Jesse Clark (b) (4) (b) (4)	21 Aug 2020 19:44:25

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:18:08**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Sep 2020 16:30:03
User entered empty.	Susan Reed (b) (4)	21 Aug 2020 19:44:25
	(b) (4)	

US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User closed query 'Per CDM: Response noted; however, per CCGs pages 15-16, ND should be recorded for WEIGHT also. Please update accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:26:09
Query 'Per CDM: Response noted; however, per CCGs pages 15-16, ND should be recorded for WEIGHT also. Please update accordingly. Thank you.' answered with 'Screening and visit 1 done on the same day.' (Site from DM).	Susan Reed (b) (4) (b) (4)	10 Sep 2020 16:30:32
User opened query 'Per CDM: Response noted; however, per CCGs pages 15-16, ND should be recorded for WEIGHT also. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 15:32:24
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 15:32:24
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Screening and visit 1 done same day' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Sep 2020 17:18:14
User entered missing code ND - Not Done; reason for change Per Query Resolution	Susan Reed (b) (4) (b) (4)	09 Sep 2020 17:18:06
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 17:10:20
User entered empty.	Jesse Clark (b) (4) (b) (4)	21 Aug 2020 19:44:25

US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:08

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Sep 2020 16:30:03
User entered empty.	Susan Reed (b) (4)	21 Aug 2020 19:44:25
	(b) (4)	



**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User accepted default value 'Pre-Dose (PREDOSE)'	Jesse Clark (b) (4) (b) (4)	21 Aug 2020 19:44:25

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	Jesse Clark (b) (4)	21 Aug 2020 19:44:25

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '21 Aug 2020'	Jesse Clark (b) (4)	21 Aug 2020 19:44:25

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '10:45'	Jesse Clark (b) (4)	21 Aug 2020 19:44:25

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered '21 Aug 2020 10:45'	System	21 Aug 2020 19:44:25

US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '98.6' F	Jesse Clark (b) (4)	21 Aug 2020 19:44:25

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Oral (Oral)'	(b) (4) Jesse Clark (b) (4) (b) (4)	21 Aug 2020 19:44:25

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered empty.	Jesse Clark (b) (4)	21 Aug 2020 19:44:25



US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 19:45:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 19:45:30
User entered '59' reason for change: Data Entry Error	Jesse Clark (b) (4)	21 Aug 2020 19:45:30
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 19:44:25
User entered empty.	Jesse Clark (b) (4)	21 Aug 2020 19:44:25
	(b) (4)	

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'bpm'	System	21 Aug 2020 19:45:30
User entered empty.	System	21 Aug 2020 19:44:25

US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 19:45:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 19:45:30
User entered '16' reason for change: Data Entry Error	Jesse Clark (b) (4)	21 Aug 2020 19:45:30
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 19:44:25
User entered empty.	Jesse Clark (b) (4)	21 Aug 2020 19:44:25
	(b) (4)	

US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'breaths/min'	System	21 Aug 2020 19:45:30
User entered empty.	System	21 Aug 2020 19:44:25

US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 19:45:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 19:45:30
User entered '140' reason for change: Data Entry Error	Jesse Clark (b) (4)	21 Aug 2020 19:45:30
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 19:44:25
User entered empty.	Jesse Clark (b) (4)	21 Aug 2020 19:44:25
	(b) (4)	

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'mmHg'	System	21 Aug 2020 19:45:30
User entered empty.	System	21 Aug 2020 19:44:25

US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 19:45:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 19:45:30
User entered '91' reason for change: Data Entry Error	Jesse Clark (b) (4)	21 Aug 2020 19:45:30
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 19:44:25
User entered empty.	Jesse Clark (b) (4)	21 Aug 2020 19:44:25
	(b) (4)	

US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'mmHg'	System	21 Aug 2020 19:45:30
User entered empty.	System	21 Aug 2020 19:44:25



US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:18:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User closed query 'Per CDM: Response noted; however, per CCGs pages 15-16, ND should be recorded for WEIGHT also. Please update accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:26:09
Query 'Per CDM: Response noted; however, per CCGs pages 15-16, ND should be recorded for WEIGHT also. Please update accordingly. Thank you.' answered with 'Screening and visit 1 done on the same day.' (Site from DM).	Susan Reed (b) (4) (b) (4)	10 Sep 2020 16:30:32
User opened query 'Per CDM: Response noted; however, per CCGs pages 15-16, ND should be recorded for WEIGHT also. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 15:32:24
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 15:32:24
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Screening and visit 1 done same day' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Sep 2020 17:18:14
User entered missing code ND - Not Done; reason for change Per Query Resolution	Susan Reed (b) (4) (b) (4)	09 Sep 2020 17:18:06
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 17:10:20
User entered empty.	Jesse Clark (b) (4) (b) (4)	21 Aug 2020 19:44:25

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:18:08**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Sep 2020 16:30:03
User entered empty.	Susan Reed (b) (4)	21 Aug 2020 19:44:25
	(b) (4)	

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User accepted default value 'Post-Dose (POSTDOSE)'	Jesse Clark (b) (4) (b) (4)	21 Aug 2020 19:44:25

US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Jesse Clark (b) (4) (b) (4)	21 Aug 2020 19:44:25

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '21 Aug 2020'	Jesse Clark (b) (4)	21 Aug 2020 19:44:25

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '12:36'	Jesse Clark (b) (4)	21 Aug 2020 19:44:25

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered '21 Aug 2020 12:36'	System	21 Aug 2020 19:44:25

US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '98.0' F	Jesse Clark (b) (4)	21 Aug 2020 19:44:25



**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Oral (Oral)'	(b) (4) Jesse Clark (b) (4) (b) (4)	21 Aug 2020 19:44:25

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered empty.	Jesse Clark (b) (4)	21 Aug 2020 19:44:25

US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 19:46:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 19:46:12
User entered '55' reason for change: Data Entry Error	Jesse Clark (b) (4)	21 Aug 2020 19:46:12
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 19:44:25
User entered empty.	System	21 Aug 2020 19:44:25
	Jesse Clark (b) (4)	21 Aug 2020 19:44:25
	(b) (4)	

US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'bpm'	System	21 Aug 2020 19:46:12
User entered empty.	System	21 Aug 2020 19:44:25

US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	21 Aug 2020 19:46:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Aug 2020 19:46:12
User entered '18' reason for change: Data Entry Error	Jesse Clark (b) (4)	21 Aug 2020 19:46:12
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	21 Aug 2020 19:44:25
User entered empty.	Jesse Clark (b) (4)	21 Aug 2020 19:44:25
	(b) (4)	

US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'breaths/min'	System	21 Aug 2020 19:46:12
User entered empty.	System	21 Aug 2020 19:44:25

US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 19:46:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 19:46:12
User entered '143' reason for change: Data Entry Error	Jesse Clark (b) (4)	21 Aug 2020 19:46:12
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 19:44:25
User entered empty.	Jesse Clark (b) (4)	21 Aug 2020 19:44:25
	(b) (4)	

US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'mmHg'	System	21 Aug 2020 19:46:12
User entered empty.	System	21 Aug 2020 19:44:25



US3682001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 19:46:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 19:46:12
User entered '83' reason for change: Data Entry Error	Jesse Clark (b) (4)	21 Aug 2020 19:46:12
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 19:44:25
User entered empty.	Jesse Clark (b) (4)	21 Aug 2020 19:44:25
	(b) (4)	

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'mmHg'	System	21 Aug 2020 19:46:12
User entered empty.	System	21 Aug 2020 19:44:25

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:18:08**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Timothy Hall (b) (4)	21 Aug 2020 18:53:04

US3682001

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '21 Aug 2020'	(b) (4) Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:53:04

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	Jesse Clark (b) (4)	21 Aug 2020 19:49:39

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered empty.	Jesse Clark (b) (4)	21 Aug 2020 19:49:39

US3682001

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered empty.	Jesse Clark (b) (4)	21 Aug 2020 19:49:39

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 19:49:39



US3682001

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '21 Aug 2020'	Jesse Clark (b) (4)	21 Aug 2020 19:49:39

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '12:06'	Jesse Clark (b) (4)	21 Aug 2020 19:49:39

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered '21 Aug 2020 12:06'	System	21 Aug 2020 19:49:39

US3682001

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Right Arm (RIGHT ARM)'	Jesse Clark (b) (4)	21 Aug 2020 19:49:39

US3682001

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'ONCE'	System	21 Aug 2020 19:49:39

US3682001

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 22:49:08

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 22:49:08



**US3682001**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '11:40'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 22:49:08

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered '21 Aug 2020 11:40'	System	21 Aug 2020 22:49:08

US3682001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:18:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4)	21 Aug 2020 22:53:25
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	21 Aug 2020 22:53:25
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 22:53:25
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	21 Aug 2020 22:52:26
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 22:52:26

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Aug 2020 22:52:26

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 22:52:26

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '11:43'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 22:52:26

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered '21 Aug 2020 11:43'	System	21 Aug 2020 22:53:25
User entered empty.	System	21 Aug 2020 22:52:26

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Aug 2020 22:52:26



US3682001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Aug 2020 22:52:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 22:52:45
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	21 Aug 2020 22:52:45
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 22:52:26
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 22:52:26

US3682001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:18:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User closed query 'Was sample collected is No, however Collection time is provided. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 22:53:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 22:53:12
User opened query 'Was sample collected is No, however Collection time is provided. Please correct.' (Site from System).	System	21 Aug 2020 22:52:45
User entered '11:43' reason for change: New Information	(b) (4), (b) (6)	21 Aug 2020 22:52:45
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 22:52:26

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered empty.	System	21 Aug 2020 22:52:26

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:59:18

**US3682001**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'I'	System	26 Aug 2020 15:59:18

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-21T12:51:28', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4563e486-2d0f-4a79-a1a6-a597c3d639b3' User entered 'Yes (Y)'	System	21 Aug 2020 19:51:48
	System	21 Aug 2020 19:51:48

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-21T12:51:36', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4563e486-2d0f-4a79-a1a6-a597c3d639b3' User entered '98.0'	System	21 Aug 2020 19:51:48
	System	21 Aug 2020 19:51:48



US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-21T12:51:39', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4563e486-2d0f-4a79-a1a6-a597c3d639b3'	System	21 Aug 2020 19:51:48
User entered 'No (N)'	System	21 Aug 2020 19:51:48

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-21T12:51:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4563e486-2d0f-4a79-a1a6-a597c3d639b3' User entered '21 Aug 2020 12:51'	System	21 Aug 2020 19:51:48
	System	21 Aug 2020 19:51:48

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '21 Aug 2020 12:26'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '21 Aug 2020 14:56'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-22T11:08:47', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '935c55a4-116e-4911-a4c0-d81bd0c9cc13' User entered 'Yes (Y)'	System	22 Aug 2020 18:09:03
	System	22 Aug 2020 18:09:03

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-22T11:08:53', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '935c55a4-116e-4911-a4c0-d81bd0c9cc13' User entered '98.4'	System	22 Aug 2020 18:09:03
	System	22 Aug 2020 18:09:03

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-22T11:08:57', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '935c55a4-116e-4911-a4c0-d81bd0c9cc13'	System	22 Aug 2020 18:09:03
User entered 'No (N)'	System	22 Aug 2020 18:09:03



**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-22T11:09:01', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '935c55a4-116e-4911-a4c0-d81bd0c9cc13'	System	22 Aug 2020 18:09:03
User entered '22 Aug 2020 11:09'	System	22 Aug 2020 18:09:03

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '21 Aug 2020 15:51'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 2'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:18:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-23T08:15:39', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c613ed90-b07c-495b-92d5-a46cd102fe66'	System	23 Aug 2020 15:15:55
User entered 'Yes (Y)'	System	23 Aug 2020 15:15:55

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:18:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-23T08:15:46', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c613ed90-b07c-495b-92d5-a46cd102fe66' User entered '97.7'	System	23 Aug 2020 15:15:55
	System	23 Aug 2020 15:15:55

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-23T08:15:49', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c613ed90-b07c-495b-92d5-a46cd102fe66'	System	23 Aug 2020 15:15:55
User entered 'No (N)'	System	23 Aug 2020 15:15:55

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-23T08:15:52', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c613ed90-b07c-495b-92d5-a46cd102fe66'	System	23 Aug 2020 15:15:55
User entered '23 Aug 2020 08:15'	System	23 Aug 2020 15:15:55



**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 3'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:18:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-24T07:57:02', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '3dfb126d-cee2-4d52-9a07-3815e54ec82d' User entered 'Yes (Y)'	System	24 Aug 2020 14:57:15
	System	24 Aug 2020 14:57:15

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:18:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-24T07:57:07', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '3dfb126d-cee2-4d52-9a07-3815e54ec82d' User entered '97.5'	System	24 Aug 2020 14:57:15
	System	24 Aug 2020 14:57:15

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-24T07:57:10', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '3dfb126d-cee2-4d52-9a07-3815e54ec82d' User entered 'No (N)'	System	24 Aug 2020 14:57:15
	System	24 Aug 2020 14:57:15

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-24T07:57:13', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '3dfb126d-cee2-4d52-9a07-3815e54ec82d' User entered '24 Aug 2020 07:57'	System	24 Aug 2020 14:57:15
	System	24 Aug 2020 14:57:15

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 19:49:39



US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:18:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 4'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-25T08:55:04', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b79101e9-923a-4c0e-8ba6-6196ea0e7e12'	System	25 Aug 2020 15:55:17
User entered 'Yes (Y)'	System	25 Aug 2020 15:55:17

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:18:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-25T08:55:09', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b79101e9-923a-4c0e-8ba6-6196ea0e7e12' User entered '97.7'	System	25 Aug 2020 15:55:17
	System	25 Aug 2020 15:55:17

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-25T08:55:12', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b79101e9-923a-4c0e-8ba6-6196ea0e7e12'	System	25 Aug 2020 15:55:17
User entered 'No (N)'	System	25 Aug 2020 15:55:17

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-25T08:55:15', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b79101e9-923a-4c0e-8ba6-6196ea0e7e12'	System	25 Aug 2020 15:55:17
User entered '25 Aug 2020 08:55'	System	25 Aug 2020 15:55:17

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 19:49:39



US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 5'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-26T08:12:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '32d806ac-e6b3-4247-bd72-9dd0c63cdd61' User entered 'Yes (Y)'	System	26 Aug 2020 15:12:38
	System	26 Aug 2020 15:12:38

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:18:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-26T08:12:06', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '32d806ac-e6b3-4247-bd72-9dd0c63cdd61' User entered '98.2'	System	26 Aug 2020 15:12:38
	System	26 Aug 2020 15:12:38

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-26T08:12:09', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '32d806ac-e6b3-4247-bd72-9dd0c63cdd61'	System	26 Aug 2020 15:12:38
User entered 'No (N)'	System	26 Aug 2020 15:12:38

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-26T08:12:13', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '32d806ac-e6b3-4247-bd72-9dd0c63cdd61' User entered '26 Aug 2020 08:12'	System	26 Aug 2020 15:12:38
	System	26 Aug 2020 15:12:38

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 6'	System	21 Aug 2020 19:49:39



**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:30:16', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '6eddecf1-6e8e-49b4-8d7a-5e571a84a05e' User entered 'Yes (Y)'	System	27 Aug 2020 15:30:45
	System	27 Aug 2020 15:30:45

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:18:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:30:20', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '6eddecf1-6e8e-49b4-8d7a-5e571a84a05e' User entered '98.0'	System	27 Aug 2020 15:30:45
	System	27 Aug 2020 15:30:45

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:30:31', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '6eddecf1-6e8e-49b4-8d7a-5e571a84a05e'	System	27 Aug 2020 15:30:45
User entered 'Yes (Y)'	System	27 Aug 2020 15:30:45

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Pt contacted, medication entered on concomitant med page.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 11:35:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Susan Reed (b) (4)	28 Aug 2020 18:18:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:30:40', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '6eddecf1-6e8e-49b4-8d7a-5e571a84a05e'	(b) (4)	
User entered '1'	System	27 Aug 2020 15:30:45
	System	27 Aug 2020 15:30:45
	System	27 Aug 2020 15:30:45

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:18:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:30:40', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '6eddecf1-6e8e-49b4-8d7a-5e571a84a05e' User entered '0'	System	27 Aug 2020 15:30:45
	System	27 Aug 2020 15:30:45

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:30:43', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '6eddecf1-6e8e-49b4-8d7a-5e571a84a05e' User entered '27 Aug 2020 08:30'	System	27 Aug 2020 15:30:45
	System	27 Aug 2020 15:30:45

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 19:49:39



US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 7'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-28T09:22:06', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '750a5b91-7679-460e-b545-d645607e8f36'	System	28 Aug 2020 16:22:21
User entered 'Yes (Y)'	System	28 Aug 2020 16:22:21

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:18:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-28T09:22:11', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '750a5b91-7679-460e-b545-d645607e8f36' User entered '96.9'	System	28 Aug 2020 16:22:21
	System	28 Aug 2020 16:22:21

US3682001

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-28T09:22:13', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '750a5b91-7679-460e-b545-d645607e8f36'	System	28 Aug 2020 16:22:21
User entered 'No (N)'	System	28 Aug 2020 16:22:21

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-28T09:22:16', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '750a5b91-7679-460e-b545-d645607e8f36' User entered '28 Aug 2020 09:22'	System	28 Aug 2020 16:22:21
	System	28 Aug 2020 16:22:21

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 19:49:39



US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-21T12:51:54', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '85a5d9e4-da8a-487e-a36b-8013ba7c1168'	System	21 Aug 2020 19:52:16
User entered 'None (1)'	System	21 Aug 2020 19:52:16

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-21T12:52:01', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '85a5d9e4-da8a-487e-a36b-8013ba7c1168'	System	21 Aug 2020 19:52:16
User entered 'No (N)'	System	21 Aug 2020 19:52:16

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-21T12:52:04', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '85a5d9e4-da8a-487e-a36b-8013ba7c1168' User entered 'No (N)'	System	21 Aug 2020 19:52:16
	System	21 Aug 2020 19:52:16

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-21T12:52:08', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '85a5d9e4-da8a-487e-a36b-8013ba7c1168'	System	21 Aug 2020 19:52:16
User entered 'None (1)'	System	21 Aug 2020 19:52:16

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-21T12:52:13', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '85a5d9e4-da8a-487e-a36b-8013ba7c1168'	System	21 Aug 2020 19:52:16
User entered '21 Aug 2020 12:52'	System	21 Aug 2020 19:52:16

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '21 Aug 2020 12:26'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '21 Aug 2020 14:56'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 19:49:39



US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-22T11:09:06', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c36aa21a-49a2-4ee9-a718-16584024e1ea' User entered 'None (1)'	System	22 Aug 2020 18:09:30
	System	22 Aug 2020 18:09:30

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-22T11:09:11', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c36aa21a-49a2-4ee9-a718-16584024e1ea' User entered 'No (N)'	System	22 Aug 2020 18:09:30
	System	22 Aug 2020 18:09:30

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-22T11:09:18', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c36aa21a-49a2-4ee9-a718-16584024e1ea' User entered 'No (N)'	System	22 Aug 2020 18:09:30
	System	22 Aug 2020 18:09:30

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-22T11:09:24', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c36aa21a-49a2-4ee9-a718-16584024e1ea' User entered 'None (1)'	System	22 Aug 2020 18:09:30
	System	22 Aug 2020 18:09:30

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-22T11:09:28', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c36aa21a-49a2-4ee9-a718-16584024e1ea' User entered '22 Aug 2020 11:09'	System	22 Aug 2020 18:09:30
	System	22 Aug 2020 18:09:30

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '21 Aug 2020 15:51'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 2'	System	21 Aug 2020 19:49:39



US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-23T08:15:56', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'f320dfb5-42ca-47f9-8d7d-3534d7a01edf'	System	23 Aug 2020 15:16:11
User entered 'None (1)'	System	23 Aug 2020 15:16:11

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-23T08:15:59', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'f320dfb5-42ca-47f9-8d7d-3534d7a01edf'	System	23 Aug 2020 15:16:11
User entered 'No (N)'	System	23 Aug 2020 15:16:11

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-23T08:16:02', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'f320dfb5-42ca-47f9-8d7d-3534d7a01edf' User entered 'No (N)'	System	23 Aug 2020 15:16:11
	System	23 Aug 2020 15:16:11

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-23T08:16:06', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'f320dfb5-42ca-47f9-8d7d-3534d7a01edf'	System	23 Aug 2020 15:16:11
User entered 'None (1)'	System	23 Aug 2020 15:16:11

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-23T08:16:08', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'f320dfb5-42ca-47f9-8d7d-3534d7a01edf' User entered '23 Aug 2020 08:16'	System	23 Aug 2020 15:16:11
	System	23 Aug 2020 15:16:11

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 3'	System	21 Aug 2020 19:49:39



US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-24T07:57:16', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4d81a592-380d-447e-b4d9-7d3f7060c264' User entered 'None (1)'	System	24 Aug 2020 14:57:35
	System	24 Aug 2020 14:57:35

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:18:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-24T07:57:19', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4d81a592-380d-447e-b4d9-7d3f7060c264'	System	24 Aug 2020 14:57:35
User entered 'No (N)'	System	24 Aug 2020 14:57:35

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-24T07:57:21', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4d81a592-380d-447e-b4d9-7d3f7060c264'	System	24 Aug 2020 14:57:35
User entered 'No (N)'	System	24 Aug 2020 14:57:35

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-24T07:57:30', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4d81a592-380d-447e-b4d9-7d3f7060c264' User entered 'None (1)'	System	24 Aug 2020 14:57:35
	System	24 Aug 2020 14:57:35

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-24T07:57:33', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4d81a592-380d-447e-b4d9-7d3f7060c264' User entered '24 Aug 2020 07:57'	System	24 Aug 2020 14:57:35
	System	24 Aug 2020 14:57:35

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 4'	System	21 Aug 2020 19:49:39



US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-25T08:55:18', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '861c9cd1-c6e8-4947-be0e-d052a2915862'	System	25 Aug 2020 15:55:39
User entered 'None (1)'	System	25 Aug 2020 15:55:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-25T08:55:21', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '861c9cd1-c6e8-4947-be0e-d052a2915862'	System	25 Aug 2020 15:55:39
User entered 'No (N)'	System	25 Aug 2020 15:55:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-25T08:55:24', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '861c9cd1-c6e8-4947-be0e-d052a2915862' User entered 'No (N)'	System	25 Aug 2020 15:55:39
	System	25 Aug 2020 15:55:39

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-25T08:55:32', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '861c9cd1-c6e8-4947-be0e-d052a2915862'	System	25 Aug 2020 15:55:39
User entered 'None (1)'	System	25 Aug 2020 15:55:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-25T08:55:34', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '861c9cd1-c6e8-4947-be0e-d052a2915862' User entered '25 Aug 2020 08:55'	System	25 Aug 2020 15:55:39
	System	25 Aug 2020 15:55:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 5'	System	21 Aug 2020 19:49:39



US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-26T08:12:18', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'da351662-c229-419d-b53e-8e6e5d00cfb9'	System	26 Aug 2020 15:12:40
User entered 'None (1)'	System	26 Aug 2020 15:12:40

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:18:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-26T08:12:23', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'da351662-c229-419d-b53e-8e6e5d00cfb9'	System	26 Aug 2020 15:12:40
User entered 'No (N)'	System	26 Aug 2020 15:12:40

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-26T08:12:26', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'da351662-c229-419d-b53e-8e6e5d00cfb9' User entered 'No (N)'	System	26 Aug 2020 15:12:40
	System	26 Aug 2020 15:12:40

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-26T08:12:28', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'da351662-c229-419d-b53e-8e6e5d00cfb9'	System	26 Aug 2020 15:12:40
User entered 'None (1)'	System	26 Aug 2020 15:12:40

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-26T08:12:34', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'da351662-c229-419d-b53e-8e6e5d00cfb9' User entered '26 Aug 2020 08:12'	System	26 Aug 2020 15:12:40
	System	26 Aug 2020 15:12:40

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 6'	System	21 Aug 2020 19:49:39



US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:30:47', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '83707916-1b98-4849-94d8-f2ac24eee89b' User entered 'None (1)'	System	27 Aug 2020 15:31:00
	System	27 Aug 2020 15:31:00

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:30:50', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '83707916-1b98-4849-94d8-f2ac24eee89b' User entered 'No (N)'	System	27 Aug 2020 15:31:00
	System	27 Aug 2020 15:31:00

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:30:52', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '83707916-1b98-4849-94d8-f2ac24eee89b' User entered 'No (N)'	System	27 Aug 2020 15:31:00
	System	27 Aug 2020 15:31:00

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:30:55', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '83707916-1b98-4849-94d8-f2ac24eee89b' User entered 'None (1)'	System	27 Aug 2020 15:31:00
	System	27 Aug 2020 15:31:00

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:30:58', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '83707916-1b98-4849-94d8-f2ac24eee89b' User entered '27 Aug 2020 08:30'	System	27 Aug 2020 15:31:00
	System	27 Aug 2020 15:31:00

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 7'	System	21 Aug 2020 19:49:39



US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-28T09:22:55', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'ad54045d-6d48-4464-b4c4-05c02383cce9'	System	28 Aug 2020 16:23:08
User entered 'None (1)'	System	28 Aug 2020 16:23:08

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-28T09:22:57', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'ad54045d-6d48-4464-b4c4-05c02383cce9' User entered 'No (N)'	System	28 Aug 2020 16:23:08
	System	28 Aug 2020 16:23:08

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-28T09:23:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'ad54045d-6d48-4464-b4c4-05c02383cce9' User entered 'No (N)'	System	28 Aug 2020 16:23:08
	System	28 Aug 2020 16:23:08

US3682001

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-28T09:23:02', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'ad54045d-6d48-4464-b4c4-05c02383cce9' User entered 'None (1)'	System	28 Aug 2020 16:23:08
	System	28 Aug 2020 16:23:08

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-28T09:23:05', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'ad54045d-6d48-4464-b4c4-05c02383cce9' User entered '28 Aug 2020 09:23'	System	28 Aug 2020 16:23:08
	System	28 Aug 2020 16:23:08

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 19:49:39



**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-21T12:52:18', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '7457bb5a-d23d-450f-9918-f902a7703ce1' User entered 'None (0)'	System	21 Aug 2020 19:52:42
	System	21 Aug 2020 19:52:42

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-21T12:52:21', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '7457bb5a-d23d-450f-9918-f902a7703ce1' User entered 'None (0)'	System	21 Aug 2020 19:52:42
	System	21 Aug 2020 19:52:42

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-21T12:52:24', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '7457bb5a-d23d-450f-9918-f902a7703ce1' User entered 'None (0)'	System	21 Aug 2020 19:52:42
	System	21 Aug 2020 19:52:42

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-21T12:52:27', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '7457bb5a-d23d-450f-9918-f902a7703ce1' User entered 'None (0)'	System	21 Aug 2020 19:52:42
	System	21 Aug 2020 19:52:42

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-21T12:52:29', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '7457bb5a-d23d-450f-9918-f902a7703ce1' User entered 'None (0)'	System	21 Aug 2020 19:52:42
	System	21 Aug 2020 19:52:42

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-21T12:52:31', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '7457bb5a-d23d-450f-9918-f902a7703ce1' User entered 'None (0)'	System	21 Aug 2020 19:52:42
	System	21 Aug 2020 19:52:42

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-21T12:52:34', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '7457bb5a-d23d-450f-9918-f902a7703ce1' User entered 'No (N)'	System	21 Aug 2020 19:52:42
	System	21 Aug 2020 19:52:42

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-21T12:52:40', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '7457bb5a-d23d-450f-9918-f902a7703ce1' User entered '21 Aug 2020 12:52'	System	21 Aug 2020 19:52:42
	System	21 Aug 2020 19:52:42



**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '21 Aug 2020 12:26'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '21 Aug 2020 14:56'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-22T11:09:33', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '82e43654-bac6-4696-9f11-b21e1f8a4424' User entered 'None (0)'	System	22 Aug 2020 18:10:06
	System	22 Aug 2020 18:10:06

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-22T11:09:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '82e43654-bac6-4696-9f11-b21e1f8a4424'	System	22 Aug 2020 18:10:06
User entered 'No interference with activity (1)'	System	22 Aug 2020 18:10:06

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-22T11:09:48', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '82e43654-bac6-4696-9f11-b21e1f8a4424' User entered 'None (0)'	System	22 Aug 2020 18:10:06
	System	22 Aug 2020 18:10:06

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-22T11:09:51', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '82e43654-bac6-4696-9f11-b21e1f8a4424' User entered 'None (0)'	System	22 Aug 2020 18:10:06
	System	22 Aug 2020 18:10:06

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-22T11:09:53', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '82e43654-bac6-4696-9f11-b21e1f8a4424' User entered 'None (0)'	System	22 Aug 2020 18:10:06
	System	22 Aug 2020 18:10:06



**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-22T11:09:55', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '82e43654-bac6-4696-9f11-b21e1f8a4424' User entered 'None (0)'	System	22 Aug 2020 18:10:06
	System	22 Aug 2020 18:10:06

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-22T11:10:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '82e43654-bac6-4696-9f11-b21e1f8a4424'	System	22 Aug 2020 18:10:06
User entered 'No (N)'	System	22 Aug 2020 18:10:06

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-22T11:10:05', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '82e43654-bac6-4696-9f11-b21e1f8a4424'	System	22 Aug 2020 18:10:06
User entered '22 Aug 2020 11:10'	System	22 Aug 2020 18:10:06

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '21 Aug 2020 15:51'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 2'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-23T08:16:18', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'e46f993a-f4f8-4527-8ed6-e28cae0d807' User entered 'None (0)'	System	23 Aug 2020 15:16:46
	System	23 Aug 2020 15:16:46

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-23T08:16:21', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'e46f993a-f4f8-4527-8ed6-e28cae0d807' User entered 'None (0)'	System	23 Aug 2020 15:16:46
	System	23 Aug 2020 15:16:46



**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-23T08:16:23', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'e46f993a-f4f8-4527-8ed6-e28caae0d807' User entered 'None (0)'	System	23 Aug 2020 15:16:46
	System	23 Aug 2020 15:16:46

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:18:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-23T08:16:26', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'e46f993a-f4f8-4527-8ed6-e28caae0d807' User entered 'None (0)'	System	23 Aug 2020 15:16:46
	System	23 Aug 2020 15:16:46

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-23T08:16:28', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'e46f993a-f4f8-4527-8ed6-e28cae0d807' User entered 'None (0)'	System	23 Aug 2020 15:16:46
	System	23 Aug 2020 15:16:46

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-23T08:16:31', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'e46f993a-f4f8-4527-8ed6-e28cae0d807' User entered 'None (0)'	System	23 Aug 2020 15:16:46
	System	23 Aug 2020 15:16:46

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-23T08:16:37', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'e46f993a-f4f8-4527-8ed6-e28caae0d807'	System	23 Aug 2020 15:16:46
User entered 'No (N)'	System	23 Aug 2020 15:16:46

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-23T08:16:41', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'e46f993a-f4f8-4527-8ed6-e28cae0d807'	System	23 Aug 2020 15:16:46
User entered '23 Aug 2020 08:16'	System	23 Aug 2020 15:16:46

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 19:49:39



**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 3'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-24T07:57:38', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b67afea0-754e-49c8-863e-bb6cb19c6580' User entered 'None (0)'	System	24 Aug 2020 14:58:01
	System	24 Aug 2020 14:58:01

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-24T07:57:41', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b67afea0-754e-49c8-863e-bb6cb19c6580' User entered 'None (0)'	System	24 Aug 2020 14:58:01
	System	24 Aug 2020 14:58:01

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:18:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-24T07:57:43', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b67afea0-754e-49c8-863e-bb6cb19c6580' User entered 'None (0)'	System	24 Aug 2020 14:58:01
	System	24 Aug 2020 14:58:01

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:18:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-24T07:57:46', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b67afea0-754e-49c8-863e-bb6cb19c6580' User entered 'None (0)'	System	24 Aug 2020 14:58:01
	System	24 Aug 2020 14:58:01

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-24T07:57:48', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b67afea0-754e-49c8-863e-bb6cb19c6580' User entered 'None (0)'	System	24 Aug 2020 14:58:01
	System	24 Aug 2020 14:58:01

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-24T07:57:50', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b67afea0-754e-49c8-863e-bb6cb19c6580' User entered 'None (0)'	System	24 Aug 2020 14:58:01
	System	24 Aug 2020 14:58:01

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-24T07:57:56', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b67afea0-754e-49c8-863e-bb6cb19c6580' User entered 'No (N)'	System	24 Aug 2020 14:58:01
	System	24 Aug 2020 14:58:01



**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-24T07:57:59', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b67afea0-754e-49c8-863e-bb6cb19c6580' User entered '24 Aug 2020 07:57'	System	24 Aug 2020 14:58:01
	System	24 Aug 2020 14:58:01

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 4'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-25T08:55:39', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '0c51138b-3116-4726-8d6b-c27c65f2e141' User entered 'None (0)'	System	25 Aug 2020 15:55:58
	System	25 Aug 2020 15:55:58

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-25T08:55:41', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '0c51138b-3116-4726-8d6b-c27c65f2e141' User entered 'None (0)'	System	25 Aug 2020 15:55:58
	System	25 Aug 2020 15:55:58

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-25T08:55:42', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '0c51138b-3116-4726-8d6b-c27c65f2e141' User entered 'None (0)'	System	25 Aug 2020 15:55:58
	System	25 Aug 2020 15:55:58

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:18:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-25T08:55:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '0c51138b-3116-4726-8d6b-c27c65f2e141' User entered 'None (0)'	System	25 Aug 2020 15:55:58
	System	25 Aug 2020 15:55:58



**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-25T08:55:47', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '0c51138b-3116-4726-8d6b-c27c65f2e141' User entered 'None (0)'	System	25 Aug 2020 15:55:58
	System	25 Aug 2020 15:55:58

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-25T08:55:49', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '0c51138b-3116-4726-8d6b-c27c65f2e141' User entered 'None (0)'	System	25 Aug 2020 15:55:58
	System	25 Aug 2020 15:55:58

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-25T08:55:53', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '0c51138b-3116-4726-8d6b-c27c65f2e141' User entered 'No (N)'	System	25 Aug 2020 15:55:58
	System	25 Aug 2020 15:55:58

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-25T08:55:56', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '0c51138b-3116-4726-8d6b-c27c65f2e141' User entered '25 Aug 2020 08:55'	System	25 Aug 2020 15:55:58
	System	25 Aug 2020 15:55:58

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 5'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-26T08:12:39', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '0b56db05-5055-423d-a63f-986aca6dbaf9'	System	26 Aug 2020 15:13:05
User entered 'No interference with activity (1)'	System	26 Aug 2020 15:13:05



**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-26T08:12:42', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '0b56db05-5055-423d-a63f-986aca6dbaf9' User entered 'None (0)'	System	26 Aug 2020 15:13:05
	System	26 Aug 2020 15:13:05

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-26T08:12:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '0b56db05-5055-423d-a63f-986aca6dbaf9' User entered 'None (0)'	System	26 Aug 2020 15:13:05
	System	26 Aug 2020 15:13:05

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-26T08:12:48', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '0b56db05-5055-423d-a63f-986aca6dbaf9' User entered 'None (0)'	System	26 Aug 2020 15:13:05
	System	26 Aug 2020 15:13:05

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-26T08:12:51', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '0b56db05-5055-423d-a63f-986aca6dbaf9' User entered 'None (0)'	System	26 Aug 2020 15:13:05
	System	26 Aug 2020 15:13:05

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-26T08:12:53', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '0b56db05-5055-423d-a63f-986aca6dbaf9' User entered 'None (0)'	System	26 Aug 2020 15:13:05
	System	26 Aug 2020 15:13:05

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-26T08:12:58', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '0b56db05-5055-423d-a63f-986aca6dbaf9'	System	26 Aug 2020 15:13:05
User entered 'No (N)'	System	26 Aug 2020 15:13:05

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-26T08:13:02', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '0b56db05-5055-423d-a63f-986aca6dbaf9' User entered '26 Aug 2020 08:13'	System	26 Aug 2020 15:13:05
	System	26 Aug 2020 15:13:05

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 19:49:39



**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 6'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:31:19', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '61c46ccd-20f5-4277-b8aa-995df3ef9e05'	System	27 Aug 2020 15:31:45
User entered 'No interference with activity (1)'	System	27 Aug 2020 15:31:45

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:31:23', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '61c46ccd-20f5-4277-b8aa-995df3ef9e05' User entered 'None (0)'	System	27 Aug 2020 15:31:45
	System	27 Aug 2020 15:31:45

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:31:25', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '61c46ccd-20f5-4277-b8aa-995df3ef9e05' User entered 'None (0)'	System	27 Aug 2020 15:31:45
	System	27 Aug 2020 15:31:45

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:18:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:31:30', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '61c46ccd-20f5-4277-b8aa-995df3ef9e05' User entered 'None (0)'	System	27 Aug 2020 15:31:45
	System	27 Aug 2020 15:31:45

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:31:32', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '61c46ccd-20f5-4277-b8aa-995df3ef9e05' User entered 'None (0)'	System	27 Aug 2020 15:31:45
	System	27 Aug 2020 15:31:45

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:31:35', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '61c46ccd-20f5-4277-b8aa-995df3ef9e05' User entered 'None (0)'	System	27 Aug 2020 15:31:45
	System	27 Aug 2020 15:31:45



US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:31:41', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '61c46ccd-20f5-4277-b8aa-995df3ef9e05' User entered 'No (N)'	System	27 Aug 2020 15:31:45
	System	27 Aug 2020 15:31:45

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-27T08:31:44', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '61c46ccd-20f5-4277-b8aa-995df3ef9e05' User entered '27 Aug 2020 08:31'	System	27 Aug 2020 15:31:45
	System	27 Aug 2020 15:31:45

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 7'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-28T09:23:09', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a8e4b0d0-9c8c-48f3-bdee-6575f6f76932'	System	28 Aug 2020 16:23:31
User entered 'None (0)'	System	28 Aug 2020 16:23:31

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-28T09:23:12', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a8e4b0d0-9c8c-48f3-bdee-6575f6f76932'	System	28 Aug 2020 16:23:31
User entered 'None (0)'	System	28 Aug 2020 16:23:31

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-28T09:23:14', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a8e4b0d0-9c8c-48f3-bdee-6575f6f76932'	System	28 Aug 2020 16:23:31
User entered 'None (0)'	System	28 Aug 2020 16:23:31



US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:18:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-28T09:23:15', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a8e4b0d0-9c8c-48f3-bdee-6575f6f76932'	System	28 Aug 2020 16:23:31
User entered 'None (0)'	System	28 Aug 2020 16:23:31

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-28T09:23:17', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a8e4b0d0-9c8c-48f3-bdee-6575f6f76932'	System	28 Aug 2020 16:23:31
User entered 'None (0)'	System	28 Aug 2020 16:23:31

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-28T09:23:19', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a8e4b0d0-9c8c-48f3-bdee-6575f6f76932'	System	28 Aug 2020 16:23:31
User entered 'None (0)'	System	28 Aug 2020 16:23:31

US3682001

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-28T09:23:23', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a8e4b0d0-9c8c-48f3-bdee-6575f6f76932'	System	28 Aug 2020 16:23:31
User entered 'No (N)'	System	28 Aug 2020 16:23:31

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-08-28T09:23:28', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a8e4b0d0-9c8c-48f3-bdee-6575f6f76932'	System	28 Aug 2020 16:23:31
User entered '28 Aug 2020 09:23'	System	28 Aug 2020 16:23:31

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	28 Aug 2020 16:44:27



**US3682001**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '28 Aug 2020'	Susan Reed (b) (4)	28 Aug 2020 16:44:27

**US3682001**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	28 Aug 2020 16:44:27

**US3682001**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	Susan Reed (b) (4)	28 Aug 2020 16:44:27

**US3682001**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	28 Aug 2020 16:44:38

**US3682001**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'I'	System	28 Aug 2020 16:44:38

**US3682001**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	11 Sep 2020 16:04:19

**US3682001**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '4 Sep 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	11 Sep 2020 16:04:19

**US3682001**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Contact Made (CONTACT MADE)'	Susan Reed (b) (4)	11 Sep 2020 16:04:19



**US3682001**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	Susan Reed (b) (4)	11 Sep 2020 16:04:19

**US3682001**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	11 Sep 2020 16:04:26

**US3682001**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'I'	System	11 Sep 2020 16:04:26

**US3682001**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	11 Sep 2020 16:04:40

**US3682001**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '11 Sep 2020'	Susan Reed (b) (4)	11 Sep 2020 16:04:40

**US3682001**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Contact Made (CONTACT MADE)'	Susan Reed (b) (4)	11 Sep 2020 16:04:40

**US3682001**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	Susan Reed (b) (4)	11 Sep 2020 16:04:40

**US3682001**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	11 Sep 2020 16:04:46



**US3682001**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'I'	System	11 Sep 2020 16:04:46

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Timothy Hall (b) (4)	18 Sep 2020 17:08:13

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '18 Sep 2020'	(b) (4) Timothy Hall (b) (4) (b) (4)	18 Sep 2020 17:08:13

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Clinic (Clinic)'	(b) (4) Timothy Hall (b) (4) (b) (4)	18 Sep 2020 17:08:13

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'VISIT2'	System	18 Sep 2020 17:08:13

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User accepted default value 'Pre-Dose (PREDOSE)'	Christopher Blades (b) (4)	18 Sep 2020 18:14:24
	(b) (4)	

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 18:14:24

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '18 Sep 2020'	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 18:14:24



**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '09:12'	Christopher Blades (b) (4)	18 Sep 2020 18:14:24

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered '18 Sep 2020 09:12'	System	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '97.2' F	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Oral (Oral)'	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 18:14:24

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered empty.	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '53'	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 18:14:24

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'bpm'	System	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '16'	(b) (4) Christopher Blades (b) (4) (b) (4)	18 Sep 2020 18:14:24



US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'breaths/min'	System	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '131'	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'mmHg'	System	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '70'	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'mmHg'	System	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User accepted default value 'Post-Dose (POSTDOSE)'	Christopher Blades (b) (4) (b) (4)	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '18 Sep 2020'	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 18:14:24



**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '10:54'	(b) (4) Christopher Blades (b) (4) (b) (4)	18 Sep 2020 18:14:24

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered '18 Sep 2020 10:54'	System	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '97.8' F	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Oral (Oral)'	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 18:14:24

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered empty.	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '49'	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 18:14:24

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'bpm'	System	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '16'	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 18:14:24



US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'breaths/min'	System	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '114'	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'mmHg'	System	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '73'	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 18:14:24

US3682001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'mmHg'	System	18 Sep 2020 18:14:24

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:18:08**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Timothy Hall (b) (4)	18 Sep 2020 17:08:27

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:18:08**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '18 Sep 2020'	(b) (4) Timothy Hall (b) (4) (b) (4)	18 Sep 2020 17:08:27

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 17:28:11



**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered empty.	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 17:28:11

US3682001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered empty.	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 17:28:11

US3682001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 17:28:11

US3682001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '18 Sep 2020'	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 17:28:11

US3682001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '10:21'	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 17:28:11

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered '18 Sep 2020 10:21'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Christopher Blades (b) (4)	18 Sep 2020 17:28:11

US3682001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'ONCE'	System	18 Sep 2020 17:28:11



US3682001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:10:24

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:10:24

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '10:13'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:10:24

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered '18 Sep 2020 10:13'	System	18 Sep 2020 18:10:24

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:18:08**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:10:40

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	18 Sep 2020 18:10:40

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:10:40



**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '10:16'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:10:40

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered '18 Sep 2020 10:16'	System	18 Sep 2020 18:10:40

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	18 Sep 2020 18:10:40

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:10:40

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:10:40

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered empty.	System	18 Sep 2020 18:10:40

US3682001

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	18 Sep 2020 19:18:12

**US3682001**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'I'	System	18 Sep 2020 19:18:12



US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T10:59:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8019fdfe-f24f-415f-8792-a4f6d65d0e9c'	System	18 Sep 2020 17:59:16
User entered 'Yes (Y)'	System	18 Sep 2020 17:59:16

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T10:59:06', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8019fdfe-f24f-415f-8792-a4f6d65d0e9c'	System	18 Sep 2020 17:59:16
User entered '97.8'	System	18 Sep 2020 17:59:16

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T10:59:09', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8019fdfe-f24f-415f-8792-a4f6d65d0e9c'	System	18 Sep 2020 17:59:16
User entered 'No (N)'	System	18 Sep 2020 17:59:16

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T10:59:14', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8019fdfe-f24f-415f-8792-a4f6d65d0e9c'	System	18 Sep 2020 17:59:16
User entered '18 Sep 2020 10:59'	System	18 Sep 2020 17:59:16

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '18 Sep 2020 10:41'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '18 Sep 2020 13:11'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 17:28:11



**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T20:40:46', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a2c5ff5e-9961-4df7-9a87-6f66136d3850'	System	19 Sep 2020 03:41:04
User entered 'Yes (Y)'	System	19 Sep 2020 03:41:04

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T20:40:52', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a2c5ff5e-9961-4df7-9a87-6f66136d3850'	System	19 Sep 2020 03:41:04
User entered '96.3'	System	19 Sep 2020 03:41:04

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T20:40:55', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a2c5ff5e-9961-4df7-9a87-6f66136d3850'	System	19 Sep 2020 03:41:04
User entered 'No (N)'	System	19 Sep 2020 03:41:04

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T20:41:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a2c5ff5e-9961-4df7-9a87-6f66136d3850'	System	19 Sep 2020 03:41:04
User entered '18 Sep 2020 20:41'	System	19 Sep 2020 03:41:04

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '18 Sep 2020 14:06'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 2'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-19T23:00:23', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '90e409a3-8afb-4a9c-8c0a-2062daec70e1' User entered 'Yes (Y)'	System	20 Sep 2020 06:00:41
	System	20 Sep 2020 06:00:41



**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-19T23:00:29', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '90e409a3-8afb-4a9c-8c0a-2062daec70e1' User entered '97.5'	System	20 Sep 2020 06:00:41
	System	20 Sep 2020 06:00:41

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-19T23:00:35', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '90e409a3-8afb-4a9c-8c0a-2062daec70e1'	System	20 Sep 2020 06:00:41
User entered 'No (N)'	System	20 Sep 2020 06:00:41

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-19T23:00:40', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '90e409a3-8afb-4a9c-8c0a-2062daec70e1' User entered '19 Sep 2020 23:00'	System	20 Sep 2020 06:00:41
	System	20 Sep 2020 06:00:41

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 3'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-20T20:10:36', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '65699af7-500a-4205-9d1d-1c5481b0d295' User entered 'Yes (Y)'	System	21 Sep 2020 03:10:57
	System	21 Sep 2020 03:10:57

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-20T20:10:41', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '65699af7-500a-4205-9d1d-1c5481b0d295' User entered '98.4'	System	21 Sep 2020 03:10:57
	System	21 Sep 2020 03:10:57



US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-20T20:10:44', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '65699af7-500a-4205-9d1d-1c5481b0d295'	System	21 Sep 2020 03:10:57
User entered 'No (N)'	System	21 Sep 2020 03:10:57

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-20T20:10:47', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '65699af7-500a-4205-9d1d-1c5481b0d295'	System	21 Sep 2020 03:10:57
User entered '20 Sep 2020 20:10'	System	21 Sep 2020 03:10:57

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 4'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-21T21:11:54', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c1ccfe43-bf59-4688-89de-feedba41ffae' User entered 'Yes (Y)'	System	22 Sep 2020 04:12:15
	System	22 Sep 2020 04:12:15

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:18:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-21T21:12:01', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c1ccfe43-bf59-4688-89de-feedba41ffae' User entered '97.8'	System	22 Sep 2020 04:12:15
	System	22 Sep 2020 04:12:15

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-21T21:12:04', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c1ccfe43-bf59-4688-89de-feedba41ffae'	System	22 Sep 2020 04:12:15
User entered 'No (N)'	System	22 Sep 2020 04:12:15



**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-21T21:12:10', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c1ccfe43-bf59-4688-89de-feedba41ffae'	System	22 Sep 2020 04:12:15
User entered '21 Sep 2020 21:12'	System	22 Sep 2020 04:12:15

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 5'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:18:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-22T22:32:56', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'bba57ab7-cb76-469d-91d7-7320c8a8c6f4' User entered 'Yes (Y)'	System	23 Sep 2020 05:33:13
	System	23 Sep 2020 05:33:13

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-22T22:33:01', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'bba57ab7-cb76-469d-91d7-7320c8a8c6f4' User entered '97.3'	System	23 Sep 2020 05:33:13
	System	23 Sep 2020 05:33:13

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-22T22:33:03', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'bba57ab7-cb76-469d-91d7-7320c8a8c6f4'	System	23 Sep 2020 05:33:13
User entered 'No (N)'	System	23 Sep 2020 05:33:13

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-22T22:33:11', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'bba57ab7-cb76-469d-91d7-7320c8a8c6f4' User entered '22 Sep 2020 22:33'	System	23 Sep 2020 05:33:13
	System	23 Sep 2020 05:33:13



**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 6'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-23T22:33:29', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a211e536-cb24-42bf-931d-25aff37cebf9' User entered 'Yes (Y)'	System	24 Sep 2020 05:33:44
	System	24 Sep 2020 05:33:44

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:18:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-23T22:33:34', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a211e536-cb24-42bf-931d-25aff37cebf9' User entered '97.8'	System	24 Sep 2020 05:33:44
	System	24 Sep 2020 05:33:44

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-23T22:33:36', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a211e536-cb24-42bf-931d-25aff37cebf9' User entered 'No (N)'	System	24 Sep 2020 05:33:44
	System	24 Sep 2020 05:33:44

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-23T22:33:39', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a211e536-cb24-42bf-931d-25aff37cebf9' User entered '23 Sep 2020 22:33'	System	24 Sep 2020 05:33:44
	System	24 Sep 2020 05:33:44

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 17:28:11



**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 7'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-24T21:52:29', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4c4e045e-68d7-403a-807a-c6afdfb722d7'	System	25 Sep 2020 04:52:46
User entered 'Yes (Y)'	System	25 Sep 2020 04:52:46

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-24T21:52:34', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4c4e045e-68d7-403a-807a-c6afdfb722d7' User entered '97.8'	System	25 Sep 2020 04:52:46
	System	25 Sep 2020 04:52:46

US3682001

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-24T21:52:38', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4c4e045e-68d7-403a-807a-c6afdfb722d7'	System	25 Sep 2020 04:52:46
User entered 'No (N)'	System	25 Sep 2020 04:52:46

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-24T21:52:42', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4c4e045e-68d7-403a-807a-c6afdfb722d7'	System	25 Sep 2020 04:52:46
User entered '24 Sep 2020 21:52'	System	25 Sep 2020 04:52:46

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 17:28:11



US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T10:59:21', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a8238b8e-038f-4230-9598-7e9904ac2b09'	System	18 Sep 2020 17:59:39
User entered 'None (1)'	System	18 Sep 2020 17:59:39

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T10:59:23', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a8238b8e-038f-4230-9598-7e9904ac2b09'	System	18 Sep 2020 17:59:39
User entered 'No (N)'	System	18 Sep 2020 17:59:39

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T10:59:26', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a8238b8e-038f-4230-9598-7e9904ac2b09'	System	18 Sep 2020 17:59:39
User entered 'No (N)'	System	18 Sep 2020 17:59:39

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T10:59:34', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a8238b8e-038f-4230-9598-7e9904ac2b09'	System	18 Sep 2020 17:59:39
User entered 'None (1)'	System	18 Sep 2020 17:59:39

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T10:59:37', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a8238b8e-038f-4230-9598-7e9904ac2b09' User entered '18 Sep 2020 10:59'	System	18 Sep 2020 17:59:39
	System	18 Sep 2020 17:59:39

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '18 Sep 2020 10:41'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '18 Sep 2020 13:11'	System	18 Sep 2020 17:28:11



US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T20:41:17', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '575d4ced-a685-4734-8e6f-8baae9b317c9'	System	19 Sep 2020 03:41:44
User entered 'None (1)'	System	19 Sep 2020 03:41:44

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T20:41:22', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '575d4ced-a685-4734-8e6f-8baae9b317c9'	System	19 Sep 2020 03:41:44
User entered 'No (N)'	System	19 Sep 2020 03:41:44

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T20:41:29', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '575d4ced-a685-4734-8e6f-8baae9b317c9'	System	19 Sep 2020 03:41:44
User entered 'No (N)'	System	19 Sep 2020 03:41:44

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T20:41:37', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '575d4ced-a685-4734-8e6f-8baae9b317c9'	System	19 Sep 2020 03:41:44
User entered 'None (1)'	System	19 Sep 2020 03:41:44

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T20:41:40', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '575d4ced-a685-4734-8e6f-8baae9b317c9' User entered '18 Sep 2020 20:41'	System	19 Sep 2020 03:41:44
	System	19 Sep 2020 03:41:44

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '18 Sep 2020 14:06'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 17:28:11



US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 2'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-19T23:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '9632a33f-96bd-42d2-99a8-cf532ac25ac5'	System	20 Sep 2020 06:00:58
User entered 'None (1)'	System	20 Sep 2020 06:00:58

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:18:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-19T23:00:47', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '9632a33f-96bd-42d2-99a8-cf532ac25ac5'	System	20 Sep 2020 06:00:58
User entered 'No (N)'	System	20 Sep 2020 06:00:58

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-19T23:00:50', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '9632a33f-96bd-42d2-99a8-cf532ac25ac5' User entered 'No (N)'	System	20 Sep 2020 06:00:58
	System	20 Sep 2020 06:00:58

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-19T23:00:53', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '9632a33f-96bd-42d2-99a8-cf532ac25ac5'	System	20 Sep 2020 06:00:58
User entered 'None (1)'	System	20 Sep 2020 06:00:58

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-19T23:00:56', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '9632a33f-96bd-42d2-99a8-cf532ac25ac5' User entered '19 Sep 2020 23:00'	System	20 Sep 2020 06:00:58
	System	20 Sep 2020 06:00:58

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 17:28:11



US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 3'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-20T20:10:51', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '5210a8cb-07f8-4934-a153-e4639a1c55ca' User entered 'None (1)'	System	21 Sep 2020 03:11:11
	System	21 Sep 2020 03:11:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-20T20:10:54', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '5210a8cb-07f8-4934-a153-e4639a1c55ca' User entered 'No (N)'	System	21 Sep 2020 03:11:11
	System	21 Sep 2020 03:11:11

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-20T20:10:57', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '5210a8cb-07f8-4934-a153-e4639a1c55ca' User entered 'No (N)'	System	21 Sep 2020 03:11:11
	System	21 Sep 2020 03:11:11

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-20T20:11:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '5210a8cb-07f8-4934-a153-e4639a1c55ca' User entered 'None (1)'	System	21 Sep 2020 03:11:11
	System	21 Sep 2020 03:11:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-20T20:11:03', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '5210a8cb-07f8-4934-a153-e4639a1c55ca' User entered '20 Sep 2020 20:11'	System	21 Sep 2020 03:11:11
	System	21 Sep 2020 03:11:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 17:28:11



US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 4'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-21T21:12:19', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '172c4ae9-31c8-448c-882b-24b36011bf47'	System	22 Sep 2020 04:13:05
User entered 'None (1)'	System	22 Sep 2020 04:13:05

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:18:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-21T21:12:23', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '172c4ae9-31c8-448c-882b-24b36011bf47'	System	22 Sep 2020 04:13:05
User entered 'No (N)'	System	22 Sep 2020 04:13:05

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-21T21:12:48', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '172c4ae9-31c8-448c-882b-24b36011bf47'	System	22 Sep 2020 04:13:05
User entered 'No (N)'	System	22 Sep 2020 04:13:05

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-21T21:12:52', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '172c4ae9-31c8-448c-882b-24b36011bf47'	System	22 Sep 2020 04:13:05
User entered 'None (1)'	System	22 Sep 2020 04:13:05

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-21T21:13:03', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '172c4ae9-31c8-448c-882b-24b36011bf47'	System	22 Sep 2020 04:13:05
User entered '21 Sep 2020 21:13'	System	22 Sep 2020 04:13:05

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 17:28:11



US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 5'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-22T22:33:15', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'dff18e9a-ebf7-423c-9d53-730ee2837395'	System	23 Sep 2020 05:33:39
User entered 'None (1)'	System	23 Sep 2020 05:33:39

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:18:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-22T22:33:18', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'dff18e9a-ebf7-423c-9d53-730ee2837395'	System	23 Sep 2020 05:33:39
User entered 'No (N)'	System	23 Sep 2020 05:33:39

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-22T22:33:23', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'dff18e9a-ebf7-423c-9d53-730ee2837395'	System	23 Sep 2020 05:33:39
User entered 'No (N)'	System	23 Sep 2020 05:33:39

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-22T22:33:30', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'dff18e9a-ebf7-423c-9d53-730ee2837395'	System	23 Sep 2020 05:33:39
User entered 'None (1)'	System	23 Sep 2020 05:33:39

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-22T22:33:34', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'dff18e9a-ebf7-423c-9d53-730ee2837395'	System	23 Sep 2020 05:33:39
User entered '22 Sep 2020 22:33'	System	23 Sep 2020 05:33:39

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 17:28:11



US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 6'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-23T22:33:46', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'bf26de7e-6db3-4897-a8aa-b8b8ea8e2fc1'	System	24 Sep 2020 05:34:08
User entered 'None (1)'	System	24 Sep 2020 05:34:08

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:18:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-23T22:33:51', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'bf26de7e-6db3-4897-a8aa-b8b8ea8e2fc1' User entered 'No (N)'	System	24 Sep 2020 05:34:08
	System	24 Sep 2020 05:34:08

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-23T22:33:54', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'bf26de7e-6db3-4897-a8aa-b8b8ea8e2fc1' User entered 'No (N)'	System	24 Sep 2020 05:34:08
	System	24 Sep 2020 05:34:08

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-23T22:34:01', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'bf26de7e-6db3-4897-a8aa-b8b8ea8e2fc1'	System	24 Sep 2020 05:34:08
User entered 'None (1)'	System	24 Sep 2020 05:34:08

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-23T22:34:04', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'bf26de7e-6db3-4897-a8aa-b8b8ea8e2fc1' User entered '23 Sep 2020 22:34'	System	24 Sep 2020 05:34:08
	System	24 Sep 2020 05:34:08

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 17:28:11



US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 7'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-24T21:52:52', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'abbfe725-0a99-47ad-80dd-27eb832cf040'	System	25 Sep 2020 04:53:11
User entered 'None (1)'	System	25 Sep 2020 04:53:11

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:18:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-24T21:52:56', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'abbfe725-0a99-47ad-80dd-27eb832cf040'	System	25 Sep 2020 04:53:11
User entered 'No (N)'	System	25 Sep 2020 04:53:11

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-24T21:52:59', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'abbfe725-0a99-47ad-80dd-27eb832cf040'	System	25 Sep 2020 04:53:11
User entered 'No (N)'	System	25 Sep 2020 04:53:11

US3682001

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-24T21:53:05', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'abbfe725-0a99-47ad-80dd-27eb832cf040'	System	25 Sep 2020 04:53:11
User entered 'None (1)'	System	25 Sep 2020 04:53:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-24T21:53:08', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'abbfe725-0a99-47ad-80dd-27eb832cf040'	System	25 Sep 2020 04:53:11
User entered '24 Sep 2020 21:53'	System	25 Sep 2020 04:53:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 17:28:11



**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T10:59:46', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '2bfc2440-e13b-4847-b9bf-7bee5bc40d30'	System	18 Sep 2020 18:00:10
User entered 'None (0)'	System	18 Sep 2020 18:00:10

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T10:59:48', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '2bfc2440-e13b-4847-b9bf-7bee5bc40d30'	System	18 Sep 2020 18:00:10
User entered 'None (0)'	System	18 Sep 2020 18:00:10

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T10:59:51', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '2bfc2440-e13b-4847-b9bf-7bee5bc40d30' User entered 'None (0)'	System	18 Sep 2020 18:00:10
	System	18 Sep 2020 18:00:10

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T10:59:53', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '2bfc2440-e13b-4847-b9bf-7bee5bc40d30' User entered 'None (0)'	System	18 Sep 2020 18:00:10
	System	18 Sep 2020 18:00:10

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T10:59:55', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '2bfc2440-e13b-4847-b9bf-7bee5bc40d30'	System	18 Sep 2020 18:00:10
User entered 'None (0)'	System	18 Sep 2020 18:00:10

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T10:59:57', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '2bfc2440-e13b-4847-b9bf-7bee5bc40d30'	System	18 Sep 2020 18:00:10
User entered 'None (0)'	System	18 Sep 2020 18:00:10

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T10:59:59', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '2bfc2440-e13b-4847-b9bf-7bee5bc40d30'	System	18 Sep 2020 18:00:10
User entered 'No (N)'	System	18 Sep 2020 18:00:10



**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T11:00:02', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '2bfc2440-e13b-4847-b9bf-7bee5bc40d30'	System	18 Sep 2020 18:00:10
User entered '18 Sep 2020 11:00'	System	18 Sep 2020 18:00:10

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '18 Sep 2020 10:41'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '18 Sep 2020 13:11'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T20:41:46', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4415f3fd-a427-4ac3-8b89-a9b5a3c6b04c'	System	19 Sep 2020 03:42:11
User entered 'No interference with activity (1)'	System	19 Sep 2020 03:42:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T20:41:49', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4415f3fd-a427-4ac3-8b89-a9b5a3c6b04c' User entered 'None (0)'	System	19 Sep 2020 03:42:11
	System	19 Sep 2020 03:42:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T20:41:52', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4415f3fd-a427-4ac3-8b89-a9b5a3c6b04c' User entered 'None (0)'	System	19 Sep 2020 03:42:11
	System	19 Sep 2020 03:42:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T20:41:54', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4415f3fd-a427-4ac3-8b89-a9b5a3c6b04c' User entered 'None (0)'	System	19 Sep 2020 03:42:11
	System	19 Sep 2020 03:42:11



**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T20:41:57', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4415f3fd-a427-4ac3-8b89-a9b5a3c6b04c' User entered 'None (0)'	System	19 Sep 2020 03:42:11
	System	19 Sep 2020 03:42:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T20:41:59', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4415f3fd-a427-4ac3-8b89-a9b5a3c6b04c' User entered 'None (0)'	System	19 Sep 2020 03:42:11
	System	19 Sep 2020 03:42:11

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T20:42:05', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4415f3fd-a427-4ac3-8b89-a9b5a3c6b04c' User entered 'No (N)'	System	19 Sep 2020 03:42:11
	System	19 Sep 2020 03:42:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-18T20:42:08', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '4415f3fd-a427-4ac3-8b89-a9b5a3c6b04c'	System	19 Sep 2020 03:42:11
User entered '18 Sep 2020 20:42'	System	19 Sep 2020 03:42:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '18 Sep 2020 14:06'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 2'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-19T23:01:03', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8584d9ff-391c-4197-98a4-2d42ec16b354'	System	20 Sep 2020 06:01:45
User entered 'No interference with activity (1)'	System	20 Sep 2020 06:01:45



**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-19T23:01:06', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8584d9ff-391c-4197-98a4-2d42ec16b354'	System	20 Sep 2020 06:01:45
User entered 'No interference with activity (1)'	System	20 Sep 2020 06:01:45

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-19T23:01:09', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8584d9ff-391c-4197-98a4-2d42ec16b354' User entered 'None (0)'	System	20 Sep 2020 06:01:45
	System	20 Sep 2020 06:01:45

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-19T23:01:12', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8584d9ff-391c-4197-98a4-2d42ec16b354' User entered 'None (0)'	System	20 Sep 2020 06:01:45
	System	20 Sep 2020 06:01:45

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-19T23:01:20', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8584d9ff-391c-4197-98a4-2d42ec16b354'	System	20 Sep 2020 06:01:45
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	20 Sep 2020 06:01:45

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-19T23:01:23', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8584d9ff-391c-4197-98a4-2d42ec16b354' User entered 'None (0)'	System	20 Sep 2020 06:01:45
	System	20 Sep 2020 06:01:45

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-19T23:01:26', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8584d9ff-391c-4197-98a4-2d42ec16b354'	System	20 Sep 2020 06:01:45
User entered 'No (N)'	System	20 Sep 2020 06:01:45

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-19T23:01:43', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8584d9ff-391c-4197-98a4-2d42ec16b354' User entered '19 Sep 2020 23:01'	System	20 Sep 2020 06:01:45
	System	20 Sep 2020 06:01:45

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 17:28:11



**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 3'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:18:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-20T20:11:06', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b2e5076b-37d2-4c8c-b568-b1b43942662b' User entered 'None (0)'	System	21 Sep 2020 03:11:35
	System	21 Sep 2020 03:11:35

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-20T20:11:08', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b2e5076b-37d2-4c8c-b568-b1b43942662b' User entered 'None (0)'	System	21 Sep 2020 03:11:35
	System	21 Sep 2020 03:11:35

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-20T20:11:11', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b2e5076b-37d2-4c8c-b568-b1b43942662b' User entered 'None (0)'	System	21 Sep 2020 03:11:35
	System	21 Sep 2020 03:11:35

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-20T20:11:13', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b2e5076b-37d2-4c8c-b568-b1b43942662b' User entered 'None (0)'	System	21 Sep 2020 03:11:35
	System	21 Sep 2020 03:11:35

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-20T20:11:16', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b2e5076b-37d2-4c8c-b568-b1b43942662b' User entered 'None (0)'	System	21 Sep 2020 03:11:35
	System	21 Sep 2020 03:11:35

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-20T20:11:18', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b2e5076b-37d2-4c8c-b568-b1b43942662b' User entered 'None (0)'	System	21 Sep 2020 03:11:35
	System	21 Sep 2020 03:11:35



US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-20T20:11:22', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b2e5076b-37d2-4c8c-b568-b1b43942662b' User entered 'No (N)'	System	21 Sep 2020 03:11:35
	System	21 Sep 2020 03:11:35

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-20T20:11:29', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b2e5076b-37d2-4c8c-b568-b1b43942662b' User entered '20 Sep 2020 20:11'	System	21 Sep 2020 03:11:35
	System	21 Sep 2020 03:11:35

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 17:28:11

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 4'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-21T21:13:16', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '45b1754d-c26b-45d7-ab2b-27ebe54da688' User entered 'None (0)'	System	22 Sep 2020 04:13:40
	System	22 Sep 2020 04:13:40

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-21T21:13:19', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '45b1754d-c26b-45d7-ab2b-27ebe54da688' User entered 'None (0)'	System	22 Sep 2020 04:13:40
	System	22 Sep 2020 04:13:40

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-21T21:13:21', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '45b1754d-c26b-45d7-ab2b-27ebe54da688' User entered 'None (0)'	System	22 Sep 2020 04:13:40
	System	22 Sep 2020 04:13:40



US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:18:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-21T21:13:24', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '45b1754d-c26b-45d7-ab2b-27ebe54da688' User entered 'None (0)'	System	22 Sep 2020 04:13:40
	System	22 Sep 2020 04:13:40

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-21T21:13:27', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '45b1754d-c26b-45d7-ab2b-27ebe54da688' User entered 'None (0)'	System	22 Sep 2020 04:13:40
	System	22 Sep 2020 04:13:40

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-21T21:13:29', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '45b1754d-c26b-45d7-ab2b-27ebe54da688' User entered 'None (0)'	System	22 Sep 2020 04:13:40
	System	22 Sep 2020 04:13:40

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-21T21:13:32', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '45b1754d-c26b-45d7-ab2b-27ebe54da688'	System	22 Sep 2020 04:13:40
User entered 'No (N)'	System	22 Sep 2020 04:13:40

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-21T21:13:38', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '45b1754d-c26b-45d7-ab2b-27ebe54da688' User entered '21 Sep 2020 21:13'	System	22 Sep 2020 04:13:40
	System	22 Sep 2020 04:13:40

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 5'	System	18 Sep 2020 17:28:11



**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-22T22:33:37', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b6ef7d31-a8ed-48c2-9426-e2fca07f6096' User entered 'None (0)'	System	23 Sep 2020 05:33:58
	System	23 Sep 2020 05:33:58

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-22T22:33:40', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b6ef7d31-a8ed-48c2-9426-e2fca07f6096' User entered 'None (0)'	System	23 Sep 2020 05:33:58
	System	23 Sep 2020 05:33:58

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:18:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-22T22:33:42', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b6ef7d31-a8ed-48c2-9426-e2fca07f6096' User entered 'None (0)'	System	23 Sep 2020 05:33:58
	System	23 Sep 2020 05:33:58

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:18:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-22T22:33:44', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b6ef7d31-a8ed-48c2-9426-e2fca07f6096' User entered 'None (0)'	System	23 Sep 2020 05:33:58
	System	23 Sep 2020 05:33:58

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-22T22:33:48', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b6ef7d31-a8ed-48c2-9426-e2fca07f6096' User entered 'None (0)'	System	23 Sep 2020 05:33:58
	System	23 Sep 2020 05:33:58

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-22T22:33:50', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b6ef7d31-a8ed-48c2-9426-e2fca07f6096' User entered 'None (0)'	System	23 Sep 2020 05:33:58
	System	23 Sep 2020 05:33:58

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-22T22:33:54', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b6ef7d31-a8ed-48c2-9426-e2fca07f6096' User entered 'No (N)'	System	23 Sep 2020 05:33:58
	System	23 Sep 2020 05:33:58

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-22T22:33:56', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b6ef7d31-a8ed-48c2-9426-e2fca07f6096' User entered '22 Sep 2020 22:33'	System	23 Sep 2020 05:33:58
	System	23 Sep 2020 05:33:58



**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 6'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-23T22:34:21', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '1ee820dc-ac59-47c0-914f-a59992c13a8f' User entered 'None (0)'	System	24 Sep 2020 05:34:48
	System	24 Sep 2020 05:34:48

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-23T22:34:27', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '1ee820dc-ac59-47c0-914f-a59992c13a8f' User entered 'None (0)'	System	24 Sep 2020 05:34:48
	System	24 Sep 2020 05:34:48

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-23T22:34:29', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '1ee820dc-ac59-47c0-914f-a59992c13a8f' User entered 'None (0)'	System	24 Sep 2020 05:34:48
	System	24 Sep 2020 05:34:48

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:18:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-23T22:34:32', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '1ee820dc-ac59-47c0-914f-a59992c13a8f' User entered 'None (0)'	System	24 Sep 2020 05:34:48
	System	24 Sep 2020 05:34:48

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-23T22:34:35', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '1ee820dc-ac59-47c0-914f-a59992c13a8f' User entered 'None (0)'	System	24 Sep 2020 05:34:48
	System	24 Sep 2020 05:34:48



**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-23T22:34:37', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '1ee820dc-ac59-47c0-914f-a59992c13a8f' User entered 'None (0)'	System	24 Sep 2020 05:34:48
	System	24 Sep 2020 05:34:48

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-23T22:34:40', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '1ee820dc-ac59-47c0-914f-a59992c13a8f' User entered 'No (N)'	System	24 Sep 2020 05:34:48
	System	24 Sep 2020 05:34:48

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-23T22:34:47', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '1ee820dc-ac59-47c0-914f-a59992c13a8f' User entered '23 Sep 2020 22:34'	System	24 Sep 2020 05:34:48
	System	24 Sep 2020 05:34:48

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	18 Sep 2020 17:28:11
User entered 'Day 7'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-24T21:53:20', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8d79231d-2c39-4106-81d6-46823c5982c6'	System	25 Sep 2020 04:53:51
User entered 'No interference with activity (1)'	System	25 Sep 2020 04:53:51

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:18:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-24T21:53:22', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8d79231d-2c39-4106-81d6-46823c5982c6' User entered 'None (0)'	System	25 Sep 2020 04:53:51
	System	25 Sep 2020 04:53:51



**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-24T21:53:24', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8d79231d-2c39-4106-81d6-46823c5982c6' User entered 'None (0)'	System	25 Sep 2020 04:53:51
	System	25 Sep 2020 04:53:51

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-24T21:53:27', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8d79231d-2c39-4106-81d6-46823c5982c6' User entered 'None (0)'	System	25 Sep 2020 04:53:51
	System	25 Sep 2020 04:53:51

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-24T21:53:29', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8d79231d-2c39-4106-81d6-46823c5982c6' User entered 'None (0)'	System	25 Sep 2020 04:53:51
	System	25 Sep 2020 04:53:51

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-24T21:53:32', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8d79231d-2c39-4106-81d6-46823c5982c6' User entered 'None (0)'	System	25 Sep 2020 04:53:51
	System	25 Sep 2020 04:53:51

US3682001

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-24T21:53:36', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8d79231d-2c39-4106-81d6-46823c5982c6'	System	25 Sep 2020 04:53:51
User entered 'No (N)'	System	25 Sep 2020 04:53:51

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-24T21:53:42', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8d79231d-2c39-4106-81d6-46823c5982c6' User entered '24 Sep 2020 21:53'	System	25 Sep 2020 04:53:51
	System	25 Sep 2020 04:53:51

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 17:28:11

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 17:28:11



**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	25 Sep 2020 04:53:51
User entered 'Day 8'	System	25 Sep 2020 04:53:51

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:18:08**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-25T21:28:16', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'f472f2d2-bc30-4029-865e-a663f53acdb0'	System	26 Sep 2020 04:28:23
User entered 'No interference with activity (1)'	System	26 Sep 2020 04:28:23

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-25T21:28:21', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'f472f2d2-bc30-4029-865e-a663f53acdb0' User entered '25 Sep 2020 21:28'	System	26 Sep 2020 04:28:23
	System	26 Sep 2020 04:28:23

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '25 Sep 2020 12:00'	System	25 Sep 2020 04:53:51

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 04:53:51

US3682001

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 09:18:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	25 Sep 2020 04:53:51
User entered 'Day 9'	System	25 Sep 2020 04:53:51

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(9)**

**Generated On: 10 Jun 2021 09:18:08**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-26T22:25:18', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '11ca9e09-1383-494a-896b-fd14c87fa8d5' User entered 'None (0)'	System	27 Sep 2020 05:25:24
	System	27 Sep 2020 05:25:24

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(9)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-26T22:25:22', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '11ca9e09-1383-494a-896b-fd14c87fa8d5'	System	27 Sep 2020 05:25:24
User entered '26 Sep 2020 22:25'	System	27 Sep 2020 05:25:24



**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(9)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 04:53:51

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(9)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 04:53:51

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	25 Sep 2020 04:53:51
User entered 'Day 8'	System	25 Sep 2020 04:53:51

US3682001

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-25T21:28:30', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'e599a896-9e1e-46b2-af9e-345f2f83b326' User entered 'No (N)'	System	26 Sep 2020 04:28:38
	System	26 Sep 2020 04:28:38

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-25T21:28:33', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'e599a896-9e1e-46b2-af9e-345f2f83b326'	System	26 Sep 2020 04:28:38
User entered '25 Sep 2020 21:28'	System	26 Sep 2020 04:28:38

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '25 Sep 2020 12:00'	System	25 Sep 2020 04:53:51

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 04:53:51

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	25 Sep 2020 04:53:51
User entered 'Day 9'	System	25 Sep 2020 04:53:51



US3682001

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:18:08

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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-26T22:25:25', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'bd6e735c-11b8-4b25-8dcc-9e7b4edecb1f' User entered 'No (N)'	System	27 Sep 2020 05:25:32
	System	27 Sep 2020 05:25:32

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-09-26T22:25:28', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'bd6e735c-11b8-4b25-8dcc-9e7b4edecb1f' User entered '26 Sep 2020 22:25'	System	27 Sep 2020 05:25:32
	System	27 Sep 2020 05:25:32

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 04:53:51

**US3682001**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:18:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 04:53:51

**US3682001**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	25 Sep 2020 17:50:20

**US3682001**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered '25 Sep 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	25 Sep 2020 17:50:20

**US3682001**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	25 Sep 2020 17:50:20

**US3682001**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered empty.	Susan Reed (b) (4)	25 Sep 2020 17:50:20



**US3682001**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:09:15
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	25 Sep 2020 17:50:25

**US3682001**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'I'	System	25 Sep 2020 17:50:25

**US3682001**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	02 Oct 2020 16:22:48

**US3682001**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '2 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	02 Oct 2020 16:22:48

**US3682001**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	02 Oct 2020 16:22:48

**US3682001**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered empty.	Susan Reed (b) (4)	02 Oct 2020 16:22:48

**US3682001**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	02 Oct 2020 16:22:52

**US3682001**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'I'	System	02 Oct 2020 16:22:52



**US3682001**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:13:36

**US3682001**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '9 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:13:36

**US3682001**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:13:36

**US3682001**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 16:13:36

US3682001

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:13:44

**US3682001**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'I'	System	09 Oct 2020 16:13:44

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Timothy Hall (b) (4) (b) (4)	16 Oct 2020 16:40:27

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '16 Oct 2020'	(b) (4) Timothy Hall (b) (4)	16 Oct 2020 16:40:27



**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Clinic (Clinic)'	(b) (4) Timothy Hall (b) (4) (b) (4)	16 Oct 2020 16:40:27

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'VISIT3'	System	16 Oct 2020 16:40:27

US3682001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	16 Oct 2020 17:51:17

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '16 Oct 2020'	(b) (4) Schuyler Thomas (b) (4)	16 Oct 2020 17:51:17

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '09:23'	(b) (4) Schuyler Thomas (b) (4)	16 Oct 2020 17:51:17

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered '16 Oct 2020 09:23'	System	16 Oct 2020 17:51:17

US3682001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '97.5' F	(b) (4) Schuyler Thomas (b) (4)	16 Oct 2020 17:51:17

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Oral (Oral)'	(b) (4) Schuyler Thomas (b) (4)	16 Oct 2020 17:51:17



**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	16 Oct 2020 17:51:17

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '72'	(b) (4) Schuyler Thomas (b) (4)	16 Oct 2020 17:51:17

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'bpm'	System	16 Oct 2020 17:51:17

US3682001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '18'	(b) (4) Schuyler Thomas (b) (4)	16 Oct 2020 17:51:17

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'breaths/min'	System	16 Oct 2020 17:51:17

US3682001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '110'	(b) (4) Schuyler Thomas (b) (4)	16 Oct 2020 17:51:17

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'mmHg'	System	16 Oct 2020 17:51:17

US3682001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '73'	(b) (4) Schuyler Thomas (b) (4)	16 Oct 2020 17:51:17



**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'mmHg'	System	16 Oct 2020 17:51:17

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:18:08**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	16 Oct 2020 17:51:31

US3682001

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '16 Oct 2020'	(b) (4) Schuyler Thomas (b) (4)	16 Oct 2020 17:51:31

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:04:26

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:04:26

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered '10:15'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:04:26



**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered '16 Oct 2020 10:15'	System	16 Oct 2020 20:04:26

US3682001

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 18:55:13
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	16 Oct 2020 17:51:36

**US3682001**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'I'	System	16 Oct 2020 17:51:36

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 64'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-10-23T09:48:20', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '6379a1ec-1056-4a98-899c-e6703827a8f7'	System	23 Oct 2020 16:48:57
User entered 'No (N)'	System	23 Oct 2020 16:48:57

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-10-23T09:48:31', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '6379a1ec-1056-4a98-899c-e6703827a8f7'	System	23 Oct 2020 16:48:57
User entered 'Yes (Y)'	System	23 Oct 2020 16:48:57

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Please 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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-10-23T09:48:42', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '6379a1ec-1056-4a98-899c-e6703827a8f7'	System	23 Oct 2020 16:48:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Oct 2020 16:48:57

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-10-23T09:48:48', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '6379a1ec-1056-4a98-899c-e6703827a8f7' User entered '23 Oct 2020 09:48:48'	System	23 Oct 2020 16:48:57
	System	23 Oct 2020 16:48:57



**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 71'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-10-28T08:27:47', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'd9571f93-547e-4dcc-9b46-dd06b1e981dd'	System	28 Oct 2020 15:28:18
User entered 'No (N)'	System	28 Oct 2020 15:28:18

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-10-28T08:28:06', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'd9571f93-547e-4dcc-9b46-dd06b1e981dd'	System	28 Oct 2020 15:28:18
User entered 'No (N)'	System	28 Oct 2020 15:28:18

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-10-28T08:28:15', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'd9571f93-547e-4dcc-9b46-dd06b1e981dd' User entered '28 Oct 2020 08:28:15'	System	28 Oct 2020 15:28:18
	System	28 Oct 2020 15:28:18

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 19:49:39



**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 78'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-11-06T16:06:43', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '9cf650f4-e7a5-4343-8aa2-593aec3bc501'	System	07 Nov 2020 00:07:23
User entered 'No (N)'	System	07 Nov 2020 00:07:23

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-11-06T16:06:46', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '9cf650f4-e7a5-4343-8aa2-593aec3bc501'	System	07 Nov 2020 00:07:23
User entered 'No (N)'	System	07 Nov 2020 00:07:23

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C53BA365-7E61-44B8-81E9-DF694C6BCB7A)', Time: '2020-11-06T16:06:50', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '9cf650f4-e7a5-4343-8aa2-593aec3bc501'	System	07 Nov 2020 00:07:23
User entered '06 Nov 2020 16:06:50'	System	07 Nov 2020 00:07:23

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:24:44
Data entry locked.	System	21 Aug 2020 19:49:39
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55
Data entry locked.	System	21 Aug 2020 19:49:39
User entered 'Day 92'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Have you been exposed to someone with 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 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Please 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 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Please 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 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Please 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 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55
Data entry locked.	System	21 Aug 2020 19:49:39
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:44:55
Data entry locked.	System	21 Aug 2020 19:49:39
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 19:49:39

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-11-19T22:51:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8bc57cef-439d-476e-97a6-c0bb594e9b49' User entered 'No (N)'	System	20 Nov 2020 06:51:57
	System	20 Nov 2020 06:51:57

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-11-19T22:51:48', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8bc57cef-439d-476e-97a6-c0bb594e9b49' User entered 'No (N)'	System	20 Nov 2020 06:51:57

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-11-19T22:51:54', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '8bc57cef-439d-476e-97a6-c0bb594e9b49' User entered '19 Nov 2020 22:51:54'	System	20 Nov 2020 06:51:57
	System	20 Nov 2020 06:51:57

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '15 Nov 2020 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '19 Nov 2020 23:59'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-11-24T12:00:47', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '755a57c4-c3c4-47a2-9c1b-cc1d3c049408' User entered 'No (N)'	System	24 Nov 2020 20:01:01
	System	24 Nov 2020 20:01:01

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-11-24T12:00:52', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '755a57c4-c3c4-47a2-9c1b-cc1d3c049408'	System	24 Nov 2020 20:01:01
User entered 'No (N)'	System	24 Nov 2020 20:01:01

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-11-24T12:00:57', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '755a57c4-c3c4-47a2-9c1b-cc1d3c049408' User entered '24 Nov 2020 12:00:57'	System	24 Nov 2020 20:01:01
	System	24 Nov 2020 20:01:01

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-02T12:39:12', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '2d62a38a-3ba9-4369-b59b-718e2c5d0f74' User entered 'Yes (Y)'	System	02 Dec 2020 22:15:17
	System	02 Dec 2020 22:15:17



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-02T12:39:16', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '2d62a38a-3ba9-4369-b59b-718e2c5d0f74'	System	02 Dec 2020 22:15:17
User entered 'No (N)'	System	02 Dec 2020 22:15:17

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-02T12:39:19', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '2d62a38a-3ba9-4369-b59b-718e2c5d0f74' User entered 'No (N)'	System	02 Dec 2020 22:15:17
	System	02 Dec 2020 22:15:17

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-02T12:39:29', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '2d62a38a-3ba9-4369-b59b-718e2c5d0f74'	System	02 Dec 2020 22:15:17
User entered 'Yes (Y)'	System	02 Dec 2020 22:15:17

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Please 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-02T12:39:33', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '2d62a38a-3ba9-4369-b59b-718e2c5d0f74'	System	02 Dec 2020 22:15:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Dec 2020 22:15:17

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-02T12:39:37', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '2d62a38a-3ba9-4369-b59b-718e2c5d0f74' User entered '02 Dec 2020 12:39:37'	System	02 Dec 2020 22:15:17
	System	02 Dec 2020 22:15:17

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-07T10:13:14', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '21a3c612-436c-42df-ab51-7c604eb7e18a' User entered 'Yes (Y)'	System	07 Dec 2020 18:13:54
	System	07 Dec 2020 18:13:54

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-07T10:13:24', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '21a3c612-436c-42df-ab51-7c604eb7e18a' User entered 'No (N)'	System	07 Dec 2020 18:13:54

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-07T10:13:27', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '21a3c612-436c-42df-ab51-7c604eb7e18a' User entered 'No (N)'	System	07 Dec 2020 18:13:54
	System	07 Dec 2020 18:13:54

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-07T10:13:33', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '21a3c612-436c-42df-ab51-7c604eb7e18a' User entered 'Yes (Y)'	System	07 Dec 2020 18:13:54
	System	07 Dec 2020 18:13:54

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-07T10:13:37', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '21a3c612-436c-42df-ab51-7c604eb7e18a'	System	07 Dec 2020 18:13:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Dec 2020 18:13:54

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-07T10:13:43', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '21a3c612-436c-42df-ab51-7c604eb7e18a' User entered '07 Dec 2020 10:13:43'	System	07 Dec 2020 18:13:54
	System	07 Dec 2020 18:13:54

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-14T14:36:36', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '3073900c-e06c-4df8-8e20-0ae03838e5ec' User entered 'No (N)'	System	14 Dec 2020 22:36:46
	System	14 Dec 2020 22:36:46

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-14T14:36:39', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '3073900c-e06c-4df8-8e20-0ae03838e5ec' User entered 'No (N)'	System	14 Dec 2020 22:36:46

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-14T14:36:43', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '3073900c-e06c-4df8-8e20-0ae03838e5ec' User entered '14 Dec 2020 14:36:43'	System	14 Dec 2020 22:36:46
	System	14 Dec 2020 22:36:46

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-22T12:07:54', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c391a2cb-0c58-4565-98e1-57eae837679c' User entered 'Yes (Y)'	System	22 Dec 2020 20:14:06
	System	22 Dec 2020 20:14:06



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-22T12:07:57', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c391a2cb-0c58-4565-98e1-57eae837679c' User entered 'No (N)'	System	22 Dec 2020 20:14:06
	System	22 Dec 2020 20:14:06

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-22T12:08:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c391a2cb-0c58-4565-98e1-57eae837679c' User entered 'No (N)'	System	22 Dec 2020 20:14:06
	System	22 Dec 2020 20:14:06

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-22T12:08:11', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c391a2cb-0c58-4565-98e1-57eae837679c' User entered 'Yes (Y)'	System	22 Dec 2020 20:14:06
	System	22 Dec 2020 20:14:06

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Please 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-22T12:08:14', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c391a2cb-0c58-4565-98e1-57eae837679c'	System	22 Dec 2020 20:14:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Dec 2020 20:14:06

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-22T12:08:17', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c391a2cb-0c58-4565-98e1-57eae837679c' User entered '22 Dec 2020 12:08:17'	System	22 Dec 2020 20:14:06
	System	22 Dec 2020 20:14:06

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-29T08:07:19', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '402fc7d2-e306-4ddb-9ac9-4469b51a4b5f' User entered 'Yes (Y)'	System	29 Dec 2020 16:07:50
	System	29 Dec 2020 16:07:50

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-29T08:07:24', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '402fc7d2-e306-4ddb-9ac9-4469b51a4b5f' User entered 'No (N)'	System	29 Dec 2020 16:07:50

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-29T08:07:28', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '402fc7d2-e306-4ddb-9ac9-4469b51a4b5f' User entered 'No (N)'	System	29 Dec 2020 16:07:50
	System	29 Dec 2020 16:07:50

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-29T08:07:34', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '402fc7d2-e306-4ddb-9ac9-4469b51a4b5f' User entered 'No (N)'	System	29 Dec 2020 16:07:50
	System	29 Dec 2020 16:07:50

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2020-12-29T08:07:46', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '402fc7d2-e306-4ddb-9ac9-4469b51a4b5f' User entered '29 Dec 2020 08:07:46'	System	29 Dec 2020 16:07:50
	System	29 Dec 2020 16:07:50

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-01-04T07:56:58', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b7dd1647-f038-4433-95a2-b9d286fecbdb' User entered 'No (N)'	System	04 Jan 2021 15:57:09

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-01-04T07:57:02', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b7dd1647-f038-4433-95a2-b9d286fecbdb' User entered 'No (N)'	System	04 Jan 2021 15:57:09

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-01-04T07:57:06', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'b7dd1647-f038-4433-95a2-b9d286fecbdb' User entered '04 Jan 2021 07:57:06'	System	04 Jan 2021 15:57:09

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-01-11T12:00:36', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'd6d876f1-b147-47ad-8505-92b195b3626f' User entered 'No (N)'	System	11 Jan 2021 20:00:50
	System	11 Jan 2021 20:00:50

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-01-11T12:00:39', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'd6d876f1-b147-47ad-8505-92b195b3626f'	System	11 Jan 2021 20:00:50
User entered 'No (N)'	System	11 Jan 2021 20:00:50



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-01-11T12:00:43', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'd6d876f1-b147-47ad-8505-92b195b3626f' User entered '11 Jan 2021 12:00:43'	System	11 Jan 2021 20:00:50
	System	11 Jan 2021 20:00:50

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-01-18T14:29:15', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '00bcb9e7-3ecc-4ba7-92bb-c9e535a8d1ae' User entered 'No (N)'	System	18 Jan 2021 22:29:25
	System	18 Jan 2021 22:29:25

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-01-18T14:29:18', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '00bcb9e7-3ecc-4ba7-92bb-c9e535a8d1ae'	System	18 Jan 2021 22:29:25
User entered 'No (N)'	System	18 Jan 2021 22:29:25

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-01-18T14:29:21', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '00bcb9e7-3ecc-4ba7-92bb-c9e535a8d1ae' User entered '18 Jan 2021 14:29:21'	System	18 Jan 2021 22:29:25
	System	18 Jan 2021 22:29:25

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-01-25T12:32:06', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a517dccc-3681-4a27-8336-de4ea9386e6c' User entered 'No (N)'	System	25 Jan 2021 20:32:16
	System	25 Jan 2021 20:32:16

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-01-25T12:32:10', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a517dccc-3681-4a27-8336-de4ea9386e6c' User entered 'No (N)'	System	25 Jan 2021 20:32:16
	System	25 Jan 2021 20:32:16

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-01-25T12:32:14', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'a517dccc-3681-4a27-8336-de4ea9386e6c' User entered '25 Jan 2021 12:32:14'	System	25 Jan 2021 20:32:16
	System	25 Jan 2021 20:32:16

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-01T11:12:37', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'f1ee3e63-4763-41d9-a4b1-89db41c3137c' User entered 'No (N)'	System	01 Feb 2021 19:12:49
	System	01 Feb 2021 19:12:49

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-01T11:12:40', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'f1ee3e63-4763-41d9-a4b1-89db41c3137c' User entered 'No (N)'	System	01 Feb 2021 19:12:49
	System	01 Feb 2021 19:12:49

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-01T11:12:46', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'f1ee3e63-4763-41d9-a4b1-89db41c3137c' User entered '01 Feb 2021 11:12:46'	System	01 Feb 2021 19:12:49
	System	01 Feb 2021 19:12:49

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T09:59:07', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered 'Yes (Y)'	System	07 Feb 2021 18:02:31
	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:24', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered 'No (N)'	System	07 Feb 2021 18:02:31
	System	07 Feb 2021 18:02:31



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:15', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered 'Yes (Y)'	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '0'	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '1'	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '0'	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '0'	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '0'	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '1'	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '1'	System	07 Feb 2021 18:02:31



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '1'	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '1'	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '0'	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '0'	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '0'	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '0'	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '0'	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '0'	System	07 Feb 2021 18:02:31



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '0'	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:45', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '0'	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Please 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:51', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1'	System	07 Feb 2021 18:02:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:00:57', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered 'No (N)'	System	07 Feb 2021 18:02:31
	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-07T10:01:23', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '30325cc5-586b-4a9a-b427-c0f8b670d0e1' User entered '07 Feb 2021 10:01:23'	System	07 Feb 2021 18:02:31
	System	07 Feb 2021 18:02:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-16T09:37:42', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '1180c432-4ec8-45d6-aa99-c0ad66f7ea35' User entered 'No (N)'	System	16 Feb 2021 17:37:52
	System	16 Feb 2021 17:37:52

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-16T09:37:44', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '1180c432-4ec8-45d6-aa99-c0ad66f7ea35' User entered 'No (N)'	System	16 Feb 2021 17:37:52
	System	16 Feb 2021 17:37:52

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-16T09:37:47', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '1180c432-4ec8-45d6-aa99-c0ad66f7ea35' User entered '16 Feb 2021 09:37:47'	System	16 Feb 2021 17:37:52
	System	16 Feb 2021 17:37:52

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-22T20:54:12', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '865d3604-05de-4757-b8ab-1f4ebbbebcc11' User entered 'No (N)'	System	23 Feb 2021 04:54:22
	System	23 Feb 2021 04:54:22

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-22T20:54:14', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '865d3604-05de-4757-b8ab-1f4ebbbecc11'	System	23 Feb 2021 04:54:22
User entered 'No (N)'	System	23 Feb 2021 04:54:22



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-02-22T20:54:20', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '865d3604-05de-4757-b8ab-1f4ebbbebcc11' User entered '22 Feb 2021 20:54:20'	System	23 Feb 2021 04:54:22
	System	23 Feb 2021 04:54:22

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-03-01T11:01:17-08:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '6c112252-a9eb-4620-b3dc-034c4d8b90d2'	System	01 Mar 2021 19:01:31
User entered 'No (N)'	System	01 Mar 2021 19:01:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-03-01T11:01:20-08:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '6c112252-a9eb-4620-b3dc-034c4d8b90d2'	System	01 Mar 2021 19:01:31
User entered 'No (N)'	System	01 Mar 2021 19:01:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-03-01T11:01:23-08:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '6c112252-a9eb-4620-b3dc-034c4d8b90d2'	System	01 Mar 2021 19:01:31
User entered '01 Mar 2021 11:01:23'	System	01 Mar 2021 19:01:31

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-03-08T10:18:05-08:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '36b0aa5c-4eef-48ca-bb18-2eb548b51ab8'	System	08 Mar 2021 18:21:11
User entered 'No (N)'	System	08 Mar 2021 18:21:11

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-03-08T10:18:08-08:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '36b0aa5c-4eef-48ca-bb18-2eb548b51ab8'	System	08 Mar 2021 18:21:11
User entered 'No (N)'	System	08 Mar 2021 18:21:11

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-03-08T10:18:14-08:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '36b0aa5c-4eef-48ca-bb18-2eb548b51ab8' User entered '08 Mar 2021 10:18:14'	System	08 Mar 2021 18:21:11
	System	08 Mar 2021 18:21:11

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-03-15T11:06:49-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '47c1f414-1e80-456e-bdc4-66cbf02849e6'	System	15 Mar 2021 18:06:58
User entered 'No (N)'	System	15 Mar 2021 18:06:58

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-03-15T11:06:52-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '47c1f414-1e80-456e-bdc4-66cbf02849e6'	System	15 Mar 2021 18:06:58
User entered 'No (N)'	System	15 Mar 2021 18:06:58

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-03-15T11:06:55-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '47c1f414-1e80-456e-bdc4-66cbf02849e6' User entered '15 Mar 2021 11:06:55'	System	15 Mar 2021 18:06:58
	System	15 Mar 2021 18:06:58

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-03-22T12:11:27-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '6a81f586-c6ad-4a8e-95dd-c1a364a4958f'	System	22 Mar 2021 19:11:37
User entered 'No (N)'	System	22 Mar 2021 19:11:37

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-03-22T12:11:30-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '6a81f586-c6ad-4a8e-95dd-c1a364a4958f'	System	22 Mar 2021 19:11:37
User entered 'No (N)'	System	22 Mar 2021 19:11:37



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-03-22T12:11:32-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '6a81f586-c6ad-4a8e-95dd-c1a364a4958f' User entered '22 Mar 2021 12:11:32'	System	22 Mar 2021 19:11:37
	System	22 Mar 2021 19:11:37

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-03-30T12:04:04-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '3b289829-8ded-42f3-ba76-17ae557508eb' User entered 'No (N)'	System	30 Mar 2021 19:07:16
	System	30 Mar 2021 19:07:16

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-03-30T12:04:09-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '3b289829-8ded-42f3-ba76-17ae557508eb'	System	30 Mar 2021 19:07:16
User entered 'No (N)'	System	30 Mar 2021 19:07:16

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-03-30T12:04:17-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '3b289829-8ded-42f3-ba76-17ae557508eb' User entered '30 Mar 2021 12:04:17'	System	30 Mar 2021 19:07:16
	System	30 Mar 2021 19:07:16

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-04-05T10:16:06-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'ed4facef-1e25-466e-a5c7-c3ff459555a3'	System	05 Apr 2021 17:16:14
User entered 'No (N)'	System	05 Apr 2021 17:16:14

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-04-05T10:16:09-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'ed4facef-1e25-466e-a5c7-c3ff459555a3'	System	05 Apr 2021 17:16:14
User entered 'No (N)'	System	05 Apr 2021 17:16:14

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-04-05T10:16:12-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'ed4facef-1e25-466e-a5c7-c3ff459555a3'	System	05 Apr 2021 17:16:14
User entered '05 Apr 2021 10:16:12'	System	05 Apr 2021 17:16:14

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-04-12T08:12:57-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'd41cf5cb-e00b-4861-8472-1438c75950a0' User entered 'No (N)'	System	12 Apr 2021 15:13:12
	System	12 Apr 2021 15:13:12

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-04-12T08:13:02-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'd41cf5cb-e00b-4861-8472-1438c75950a0'	System	12 Apr 2021 15:13:12
User entered 'No (N)'	System	12 Apr 2021 15:13:12

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-04-12T08:13:05-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'd41cf5cb-e00b-4861-8472-1438c75950a0'	System	12 Apr 2021 15:13:12
User entered '12 Apr 2021 08:13:05'	System	12 Apr 2021 15:13:12

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-04-19T10:46:11-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c84ad76f-43e8-4084-9b8a-948030adcfcf' User entered 'No (N)'	System	19 Apr 2021 17:46:20
	System	19 Apr 2021 17:46:20

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-04-19T10:46:14-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c84ad76f-43e8-4084-9b8a-948030adcfcf' User entered 'No (N)'	System	19 Apr 2021 17:46:20
	System	19 Apr 2021 17:46:20



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-04-19T10:46:17-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'c84ad76f-43e8-4084-9b8a-948030adcfcf'	System	19 Apr 2021 17:46:20
User entered '19 Apr 2021 10:46:17'	System	19 Apr 2021 17:46:20

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-04-26T11:48:51-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'f781b38e-0cfc-45cd-91b1-5311590401f9'	System	26 Apr 2021 18:48:59
User entered 'No (N)'	System	26 Apr 2021 18:48:59

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-04-26T11:48:53-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'f781b38e-0cfc-45cd-91b1-5311590401f9'	System	26 Apr 2021 18:48:59
User entered 'No (N)'	System	26 Apr 2021 18:48:59

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-04-26T11:48:56-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: 'f781b38e-0cfc-45cd-91b1-5311590401f9'	System	26 Apr 2021 18:48:59
User entered '26 Apr 2021 11:48:56'	System	26 Apr 2021 18:48:59

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-05-03T12:46:32-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '5770af2b-be7f-4484-9b88-6237377ce584'	System	03 May 2021 19:46:40
User entered 'No (N)'	System	03 May 2021 19:46:40

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Have you been exposed to someone with 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 (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-05-03T12:46:34-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '5770af2b-be7f-4484-9b88-6237377ce584'	System	03 May 2021 19:46:40
User entered 'No (N)'	System	03 May 2021 19:46:40

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-05-03T12:46:37-07:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '5770af2b-be7f-4484-9b88-6237377ce584'	System	03 May 2021 19:46:40
User entered '03 May 2021 12:46:37'	System	03 May 2021 19:46:40

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:44:55



**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:18:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:44:55
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:44:55

**US3682001**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:18:08**

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)	25 Apr 2021 13:56:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-03-01T11:01:30-08:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '5ae594d6-8f7f-47d4-a2b2-a9cac42de850'	System	01 Mar 2021 19:01:53
User entered 'No (N)'	System	01 Mar 2021 19:01:53

**US3682001**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:56:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B412192D-223A-457E-B328-7C2F81ABDEAA)', Time: '2021-03-01T11:01:33-08:00', User OID: 'PatientReportedOutcome (US3682001)', ODM File OID: '5ae594d6-8f7f-47d4-a2b2-a9cac42de850'	System	01 Mar 2021 19:01:53
User entered '01 Mar 2021 11:01:33'	System	01 Mar 2021 19:01:53



**US3682001**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:08:20
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	13 Nov 2020 17:25:56

**US3682001**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:08:20
User entered '13 Nov 2020'	Susan Reed (b) (4)	13 Nov 2020 17:25:56

**US3682001**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:08:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	13 Nov 2020 17:25:56

**US3682001**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:08:20
User entered empty.	Susan Reed (b) (4)	13 Nov 2020 17:25:56

**US3682001**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:08:20
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	13 Nov 2020 17:26:06

**US3682001**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:57:50
User entered 'I'	System	13 Nov 2020 17:26:06

**US3682001**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	Susan Reed (b) (4)	18 Dec 2020 16:59:34

**US3682001**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '18 Dec 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	18 Dec 2020 16:59:34



**US3682001**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4)	18 Dec 2020 16:59:34

**US3682001**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered empty.	Susan Reed (b) (4)	18 Dec 2020 16:59:34

**US3682001**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	18 Dec 2020 16:59:41

**US3682001**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User entered 'I'	System	18 Dec 2020 16:59:41

**US3682001**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	15 Jan 2021 18:46:41

**US3682001**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '15 Jan 2021'	Mitchell Stern (b) (4)	15 Jan 2021 18:46:41

**US3682001**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Contact Made (CONTACT MADE)'	Mitchell Stern (b) (4)	15 Jan 2021 18:46:41

**US3682001**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered empty.	(b) (4) Mitchell Stern (b) (4)	15 Jan 2021 18:46:41



**US3682001**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	15 Jan 2021 18:46:45

**US3682001**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User entered 'I'	System	15 Jan 2021 18:46:45

**US3682001**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	12 Feb 2021 19:08:04

**US3682001**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '12 Feb 2021'	Mitchell Stern (b) (4)	12 Feb 2021 19:08:04

**US3682001**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Contact Made (CONTACT MADE)'	Mitchell Stern (b) (4)	12 Feb 2021 19:08:04

**US3682001**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered empty.	(b) (4) Mitchell Stern (b) (4)	12 Feb 2021 19:08:04

**US3682001**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	12 Feb 2021 19:08:09

**US3682001**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User entered 'I'	System	12 Feb 2021 19:08:09



**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4)	05 Mar 2021 17:40:16

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '5 Mar 2021'	Simone Riley (b) (4)	05 Mar 2021 17:40:16

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Clinic (Clinic)'	Simone Riley (b) (4)	05 Mar 2021 17:40:16

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User entered 'VISIT4'	System	05 Mar 2021 17:40:16

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:35:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:56:56

US3682001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:35:35
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	30 Mar 2021 15:57:05
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	30 Mar 2021 15:57:05
User entered '5 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 15:57:05
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Mar 2021 15:56:56
User entered '19 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 15:56:56

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:35:35
User entered '09:07'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:56:56

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User entered '5 Mar 2021 09:07'	System	30 Mar 2021 15:57:05
User entered '19 Mar 2021 09:07'	System	30 Mar 2021 15:56:56



**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:35:35
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:56:56

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:35:35
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:56:56

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:35:35
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:56:56

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:35:35
User entered '64'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:56:56

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User entered 'bpm'	System	30 Mar 2021 15:56:56

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:35:35
User entered '12'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:56:56

US3682001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User entered 'breaths/min'	System	30 Mar 2021 15:56:56

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:35:35
User entered '126'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:56:56



**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User entered 'mmHg'	System	30 Mar 2021 15:56:56

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:35:35
User entered '75'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:56:56

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User entered 'mmHg'	System	30 Mar 2021 15:56:56

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:18:08**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	Simone Riley (b) (4)	05 Mar 2021 17:40:25

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:18:08**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '5 Mar 2021'	Simone Riley (b) (4)	05 Mar 2021 17:40:25

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:35:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 22:33:32



**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:35:35
User entered '5 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 22:33:32

US3682001

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:18:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:35:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Mar 2021 22:33:51
User entered '09:24' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 22:33:51
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Mar 2021 22:33:32
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 22:33:32

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User entered '5 Mar 2021 09:24'	System	17 Mar 2021 22:33:51
User entered empty.	System	17 Mar 2021 22:33:32

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	Simone Riley (b) (4)	05 Mar 2021 17:40:29

**US3682001**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:55:23
User entered 'I'	System	05 Mar 2021 17:40:29

**US3682001**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	16 Apr 2021 22:48:16
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	16 Apr 2021 16:51:04
	(b) (4)	

**US3682001**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	16 Apr 2021 22:48:16
	(b) (4)	
User entered '16 Apr 2021'	Mitchell Stern (b) (4)	16 Apr 2021 16:51:04
	(b) (4)	

**US3682001**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	16 Apr 2021 22:48:16
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Mitchell Stern (b) (4)	16 Apr 2021 16:51:04
	(b) (4)	



**US3682001**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	16 Apr 2021 22:48:16
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	16 Apr 2021 16:51:04
	(b) (4)	

**US3682001**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	16 Apr 2021 22:48:16
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	16 Apr 2021 16:51:10
	(b) (4)	

**US3682001**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 16:51:10

**US3682001**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 19:21:38

**US3682001**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '8 Jan 2021'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 19:21:38

**US3682001**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Clinic (Clinic)'	Christopher Blades (b) (4)	08 Jan 2021 19:21:38

**US3682001**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 19:21:38

**US3682001**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:18:08**

**Date of updated informed consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '8 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Simone Riley (b) (4)	03 Feb 2021 21:26:36
User entered '6 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Christopher Blades (b) (4)	25 Jan 2021 21:45:12
User entered '8 Jan 2021'	(b) (4)	
	Christopher Blades (b) (4)	08 Jan 2021 19:21:58
	(b) (4)	



**US3682001**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:18:08**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:35:35
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:17:02

**US3682001**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:18:08**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 19:21:58

**US3682001**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:18:08**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:35:35
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:17:02

US3682001

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

Form: Unblinding

Generated On: 10 Jun 2021 09:18:08

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '8 Jan 2021'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 19:21:58

**US3682001**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:18:08**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Placebo (Placebo)'	Christopher Blades (b) (4)	08 Jan 2021 19:21:58

**US3682001**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:18:08**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 12:33:43
User entered 'Placebo (Placebo)'	Christopher Blades (b) (4)	08 Jan 2021 19:21:58
	(b) (4)	

**US3682001**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:18:08**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 12:33:43
User entered 'Placebo (Placebo)'	Christopher Blades (b) (4)	08 Jan 2021 19:21:58
	(b) (4)	

**US3682001**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:18:08**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	Christopher Blades (b) (4)	08 Jan 2021 19:21:58



**US3682001**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:18:08**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '1'	System	08 Jan 2021 19:21:58

**US3682001**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'I'	System	08 Jan 2021 19:21:58

**US3682001**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:18:08**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered missing code ND - Not Done.	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:18:08**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered missing code ND - Not Done.	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:18:08**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered empty.	System	08 Jan 2021 21:40:16
DataPoint set to visible.	System	08 Jan 2021 19:21:58

**US3682001**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:18:08**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered missing code ND - Not Done.	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:18:08**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered missing code ND - Not Done.	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:18:08**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered empty.	System	08 Jan 2021 21:40:16
DataPoint set to visible.	System	08 Jan 2021 19:21:58



**US3682001**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User accepted default value 'Pre-Dose (PREDOSE)'	Christopher Blades (b) (4)	08 Jan 2021 21:40:16
	(b) (4)	

**US3682001**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '8 Jan 2021'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '10:26'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '8 Jan 2021 10:26'	System	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '97.1' F	Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Oral (Oral)'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered empty.	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16



**US3682001**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '64'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'bpm'	System	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '16'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'breaths/min'	System	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '144'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'mmHg'	System	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '74'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'mmHg'	System	08 Jan 2021 21:40:16



**US3682001**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:18:08**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered missing code ND - Not Done.	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:18:08**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered missing code ND - Not Done.	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:18:08**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered empty.	System	08 Jan 2021 21:40:16
DataPoint set to visible.	System	08 Jan 2021 19:21:58

**US3682001**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User accepted default value 'Post-Dose (POSTDOSE)'	Christopher Blades (b) (4) (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '8 Jan 2021'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '11:46'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '8 Jan 2021 11:46'	System	08 Jan 2021 21:40:16



**US3682001**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '97.8' F	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Oral (Oral)'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered empty.	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '65'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'bpm'	System	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '16'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'breaths/min'	System	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '136'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16



**US3682001**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'mmHg'	System	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '87'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'mmHg'	System	08 Jan 2021 21:40:16

**US3682001**

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

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:18:08**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 19:22:09

**US3682001**

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

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:18:08**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '8 Jan 2021'	Christopher Blades (b) (4)	08 Jan 2021 19:22:09

**US3682001**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 19:27:34

**US3682001**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered empty.	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 19:27:34

**US3682001**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered empty.	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 19:27:34



**US3682001**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'mRNA-1273'	System	08 Jan 2021 19:27:34
DataPoint set to visible.	System	08 Jan 2021 19:21:58

US3682001

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

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '8 Jan 2021'	Christopher Blades (b) (4)	08 Jan 2021 19:27:34

US3682001

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

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '11:14'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 19:27:34

**US3682001**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '8 Jan 2021 11:14'	System	08 Jan 2021 19:27:34

**US3682001**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Right Arm (RIGHT ARM)'	Christopher Blades (b) (4)	08 Jan 2021 19:27:34

**US3682001**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'ONCE'	System	08 Jan 2021 19:27:34

**US3682001**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'INTRAMUSCULAR'	System	08 Jan 2021 19:27:34

**US3682001**

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

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:25:15



**US3682001**

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

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '08 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:25:15

**US3682001**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '10:36'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:25:15

**US3682001**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '08 Jan 2021 10:36'	System	08 Jan 2021 20:25:15

**US3682001**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:18:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:25:33

**US3682001**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:18:08**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '08 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:25:33

**US3682001**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:18:08**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '10:40'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:25:33

**US3682001**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:18:08**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '08 Jan 2021 10:40'	System	08 Jan 2021 20:25:33

**US3682001**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	08 Jan 2021 19:27:43



**US3682001**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'I'	System	08 Jan 2021 19:27:43

**US3682001**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:02:58
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:08:20
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	15 Jan 2021 18:47:02

**US3682001**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:02:58
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:08:20
User entered '15 Jan 2021'	Mitchell Stern (b) (4)	15 Jan 2021 18:47:02

**US3682001**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:02:58
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:08:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mitchell Stern (b) (4)	15 Jan 2021 18:47:02

**US3682001**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:02:58
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:08:20
User entered empty.	(b) (4) Mitchell Stern (b) (4)	15 Jan 2021 18:47:02

**US3682001**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:02:58
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:08:20
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4)	15 Jan 2021 18:47:08

**US3682001**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:02:58
User entered 'I'	System	15 Jan 2021 18:47:08

**US3682001**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:02:58
User entered '1'	System	15 Jan 2021 18:47:08
DataPoint set to visible.	System	15 Jan 2021 18:47:08



**US3682001**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:06:51
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	Christopher Blades (b) (4)	05 Feb 2021 18:36:04

US3682001

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:06:51
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '5 Feb 2021'	Christopher Blades (b) (4)	05 Feb 2021 18:36:04

US3682001

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:18:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:06:51
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Clinic (Clinic)'	Christopher Blades (b) (4)	05 Feb 2021 18:36:04

**US3682001**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'OLD29'	System	05 Feb 2021 18:36:04

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User accepted default value 'Pre-Dose (PREDOSE)'	Christopher Blades (b) (4)	05 Feb 2021 18:37:07
	(b) (4)	

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '5 Feb 2021'	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

**US3682001**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '09:15'	Christopher Blades (b) (4)	05 Feb 2021 18:37:07



**US3682001**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '5 Feb 2021 09:15'	System	05 Feb 2021 18:37:07

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '98.2' F	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Oral (Oral)'	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered empty.	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

**US3682001**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '60'	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

**US3682001**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'bpm'	System	05 Feb 2021 18:37:07

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '12'	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

**US3682001**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'breaths/min'	System	05 Feb 2021 18:37:07



US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '155'	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

**US3682001**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'mmHg'	System	05 Feb 2021 18:37:07

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:18:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '82'	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

**US3682001**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'mmHg'	System	05 Feb 2021 18:37:07

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User accepted default value 'Post-Dose (POSTDOSE)'	Christopher Blades (b) (4) (b) (4)	05 Feb 2021 18:37:07

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '5 Feb 2021'	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

**US3682001**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '10:09'	Christopher Blades (b) (4)	05 Feb 2021 18:37:07



**US3682001**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '5 Feb 2021 10:09'	System	05 Feb 2021 18:37:07

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '97.7' F	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Oral (Oral)'	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered empty.	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

**US3682001**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '55'	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

**US3682001**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'bpm'	System	05 Feb 2021 18:37:07

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '12'	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

**US3682001**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'breaths/min'	System	05 Feb 2021 18:37:07



US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '149'	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

**US3682001**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'mmHg'	System	05 Feb 2021 18:37:07

US3682001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:18:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:08:55
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '76'	Christopher Blades (b) (4)	05 Feb 2021 18:37:07

**US3682001**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'mmHg'	System	05 Feb 2021 18:37:07

US3682001

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:13:11
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Yes (Y)'	Christopher Blades (b) (4)	05 Feb 2021 18:37:14

US3682001

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:18:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:13:11
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '5 Feb 2021'	Christopher Blades (b) (4)	05 Feb 2021 18:37:14

US3682001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:14:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Yes (Y)'	Christopher Blades (b) (4)	05 Feb 2021 18:38:23

US3682001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:14:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Christopher Blades (b) (4)	05 Feb 2021 18:38:23



US3682001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:14:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Christopher Blades (b) (4)	05 Feb 2021 18:38:23

**US3682001**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'mRNA-1273'	System	05 Feb 2021 18:38:23
DataPoint set to visible.	System	15 Jan 2021 18:47:08

US3682001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:14:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '5 Feb 2021'	Christopher Blades (b) (4)	05 Feb 2021 18:38:23

US3682001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:14:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '09:38'	Christopher Blades (b) (4)	05 Feb 2021 18:38:23

**US3682001**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered '5 Feb 2021 09:38'	System	05 Feb 2021 18:38:23

US3682001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:14:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Right Arm (RIGHT ARM)'	Christopher Blades (b) (4)	05 Feb 2021 18:38:23

US3682001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:18:08

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:14:55
User entered 'ONCE'	System	05 Feb 2021 18:38:23

**US3682001**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:18:08**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'INTRAMUSCULAR'	System	05 Feb 2021 18:38:23



US3682001

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:18:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:17:11
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Yes (Y)'	Christopher Blades (b) (4)	05 Feb 2021 18:38:31

**US3682001**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:38
User entered 'I'	System	05 Feb 2021 18:38:31

**US3682001**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	12 Feb 2021 19:06:09

**US3682001**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '12 Feb 2021'	Mitchell Stern (b) (4)	12 Feb 2021 19:06:09

**US3682001**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Contact Made (CONTACT MADE)'	Mitchell Stern (b) (4)	12 Feb 2021 19:06:09

**US3682001**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:18:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered empty.	(b) (4) Mitchell Stern (b) (4) (b) (4)	12 Feb 2021 19:06:09

**US3682001**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:38
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	12 Feb 2021 19:06:14

**US3682001**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:18:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:38
User entered 'I'	System	12 Feb 2021 19:06:14



**US3682001**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	05 Mar 2021 17:40:42

**US3682001**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '5 Mar 2021'	(b) (4) Simone Riley (b) (4) (b) (4)	05 Mar 2021 17:40:42

**US3682001**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

[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 06:05:27
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Clinic (Clinic)'	(b) (4) Simone Riley (b) (4) (b) (4)	05 Mar 2021 17:40:42

**US3682001**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:18:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User entered 'OLD57'	System	05 Mar 2021 17:40:42

US3682001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:18:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User closed query 'Visit 4 Day 209 and Visit OL-D57 are both dated 05Mar2021. However, the data on the Vital Signs in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 06:32:26
Query 'Visit 4 Day 209 and Visit OL-D57 are both dated 05Mar2021. However, the data on the Vital Signs in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' answered with 'reviewed and updated' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:57:41
User opened query 'Visit 4 Day 209 and Visit OL-D57 are both dated 05Mar2021. However, the data on the Vital Signs in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 00:42:13
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4)	05 Mar 2021 17:41:13

**US3682001**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '5 Mar 2021'	(b) (4) Simone Riley (b) (4) (b) (4)	05 Mar 2021 17:41:13

**US3682001**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '9:07'	(b) (4) Simone Riley (b) (4) (b) (4)	05 Mar 2021 17:41:13

**US3682001**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User entered '5 Mar 2021 9:07'	System	05 Mar 2021 17:41:13



**US3682001**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '98.8' F	(b) (4) Simone Riley (b) (4) (b) (4)	05 Mar 2021 17:41:13

**US3682001**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Oral (Oral)'	(b) (4) Simone Riley (b) (4) (b) (4)	05 Mar 2021 17:41:13

**US3682001**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered empty.	(b) (4) Simone Riley (b) (4) (b) (4)	05 Mar 2021 17:41:13

**US3682001**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '64'	(b) (4) Simone Riley (b) (4) (b) (4)	05 Mar 2021 17:41:13

**US3682001**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User entered 'bpm'	System	05 Mar 2021 17:41:13

**US3682001**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '12'	(b) (4) Simone Riley (b) (4) (b) (4)	05 Mar 2021 17:41:13

**US3682001**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User entered 'breaths/min'	System	05 Mar 2021 17:41:13

**US3682001**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '126'	(b) (4) Simone Riley (b) (4) (b) (4)	05 Mar 2021 17:41:13



**US3682001**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User entered 'mmHg'	System	05 Mar 2021 17:41:13

**US3682001**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '75'	(b) (4) Simone Riley (b) (4) (b) (4)	05 Mar 2021 17:41:13

**US3682001**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User entered 'mmHg'	System	05 Mar 2021 17:41:13

**US3682001**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27

**US3682001**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:18:08**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27

**US3682001**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:18:08**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	05 Mar 2021 17:41:22

**US3682001**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:18:08**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '5 Mar 2021'	(b) (4) Simone Riley (b) (4) (b) (4)	05 Mar 2021 17:41:22

**US3682001**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 20:03:39



**US3682001**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '05 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 20:03:39

**US3682001**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
User entered '09:24'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 20:03:39

**US3682001**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:18:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:27
User entered '05 Mar 2021 09:24'	System	05 Mar 2021 20:03:39

US3682001

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:18:08

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:13:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:48
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 1 - 18Sep2020; end date: Day 8 - 25Sep2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. '(Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:01:53
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 1 - 18Sep2020; end date: Day 8 - 25Sep2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.	(b) (4), (b) (6)	09 Feb 2021 18:07:38
' answered with 'AE eCRF updated' (Site from DM). User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 1 - 18Sep2020; end date: Day 8 - 25Sep2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. '(Site from DM).	(b) (4), (b) (6)	08 Feb 2021 07:47:09
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:36:42

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27

US3682001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:13:43
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 16:44:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 16:44:23
Data point term sent to Coder	System	09 Oct 2020 16:43:33
User entered 'Headache'	Susan Reed (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:13:45
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	Susan Reed (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:13:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:43:12



US3682001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:13:54
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	Susan Reed (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:13:56
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '3 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:00
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
User entered empty.	System	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:07
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '4 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
User entered empty.	System	09 Oct 2020 16:43:12



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:15
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Susan Reed (b) (4)	09 Oct 2020 16:43:12
	(b) (4)	

US3682001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:16
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:19
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Susan Reed (b) (4)	09 Oct 2020 16:43:12

US3682001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:21
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Susan Reed (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:23
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Susan Reed (b) (4)	09 Oct 2020 16:43:12

US3682001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:25
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:43:12

US3682001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:28
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:30
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 16:43:12



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:32
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:34
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Susan Reed (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:36
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Susan Reed (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:39
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Susan Reed (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:45
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:47
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:49
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'None (NONE)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Susan Reed (b) (4)	09 Oct 2020 16:43:12



US3682001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:18:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:54
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'l'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:57
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Susan Reed (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:00
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
User entered '0'	System	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27
User entered '0'	System	09 Oct 2020 16:43:12

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:08:27



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11

US3682001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:11
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy cervical - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 04:26:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 04:26:40
User closed query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 19:50:09
Data point term sent to Coder	System	03 Nov 2020 01:10:19
Query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. ' answered with 'updated' (Site from DM).	Susan Reed (b) (4)	03 Nov 2020 01:10:18
User entered 'LYMPHADENOPATHY - CERVICAL - bilateral' reason for change: Data Entry Error	Susan Reed (b) (4)	03 Nov 2020 01:09:57
User opened query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 00:10:01

US3682001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:08

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this AE pertains to Lymphadenopathy. If yes, please update to reflect Lymphadenopathy and the location. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 00:09:56
Data point term sent to Coder	System	02 Nov 2020 17:56:18
Query 'Per DM CLR: Please review if this AE pertains to Lymphadenopathy. If yes, please update to reflect Lymphadenopathy and the location. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'updated' (Site from DM).	Susan Reed (b) (4)	02 Nov 2020 17:55:58
Coding entries removed.	(b) (4)	
	Susan Reed (b) (4)	02 Nov 2020 17:55:50
User entered 'Lymphadenopathy - cervical' reason for change: Data Entry Error	(b) (4)	02 Nov 2020 17:55:50
User opened query 'Per DM CLR: Please review if this AE pertains to Lymphadenopathy. If yes, please update to reflect Lymphadenopathy and the location. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 08:53:25
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy cervical - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 21:22:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 21:22:24
Data point term sent to Coder	System	09 Oct 2020 20:53:23
User entered 'Swollen neck glands'	Susan Reed (b) (4)	09 Oct 2020 20:52:29
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:13
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:19
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 20:52:29

US3682001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:21
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	Susan Reed (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:28
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '3 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:30
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 20:52:29



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
User entered empty.	System	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:34
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:36
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '4 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:38
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
User entered empty.	System	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:41
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Susan Reed (b) (4)	09 Oct 2020 20:52:29
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:45
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:47
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Susan Reed (b) (4)	09 Oct 2020 20:52:29



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:49
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Susan Reed (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:53
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Susan Reed (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 20:52:29

US3682001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:18:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:56
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:58
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:00
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Susan Reed (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:04
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Susan Reed (b) (4)	09 Oct 2020 20:52:29



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:06
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Susan Reed (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:17
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Not Related (NOT RELATED)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:19
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:21
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'None (NONE)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:23
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Susan Reed (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:25
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'I'	Susan Reed (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:30
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Susan Reed (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:34
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Susan Reed (b) (4) (b) (4)	09 Oct 2020 20:52:29



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:37
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:38
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
User entered '0'	System	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11
User entered '0'	System	09 Oct 2020 20:52:29

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39

US3682001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:48
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Hypoaesthesia, LLT: Numbness of upper extremities - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:54:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:54:37
Data point term sent to Coder	System	16 Oct 2020 17:00:45
User entered 'numbness in L arm'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:52
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:54
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

US3682001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:56
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:17:06
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '16 Oct 2020'	(b) (4) Timothy Hall (b) (4) (b) (4)	16 Oct 2020 17:00:11

US3682001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:17:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	16 Oct 2020 17:03:11
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Oct 2020 17:03:11
User entered empty; reason for change Data Entry Error	Timothy Hall (b) (4)	16 Oct 2020 17:03:11
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'done' (Site from System).	Timothy Hall (b) (4)	16 Oct 2020 17:02:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Oct 2020 17:02:35
User entered ':00' (non-conformant).	Timothy Hall (b) (4)	16 Oct 2020 17:02:35
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	16 Oct 2020 17:00:11
User entered '03:00'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
User entered empty.	System	16 Oct 2020 17:03:11
User entered '16 Oct 2020 :00' (non-conformant).	System	16 Oct 2020 17:02:35
User entered '16 Oct 2020 03:00'	System	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:17:15
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:17:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '16 Oct 2020'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:08

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:17:29
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	16 Oct 2020 17:02:35
User entered empty; reason for change Data Entry Error	Timothy Hall (b) (4)	16 Oct 2020 17:02:35
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	16 Oct 2020 17:00:11
User entered '07:00'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
User entered empty.	System	16 Oct 2020 17:02:35
User entered '16 Oct 2020 07:00'	System	16 Oct 2020 17:00:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:08

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:17:42
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:17:46
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	(b) (4) Timothy Hall (b) (4) (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:17:48
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:17:51
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:17:56
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:17:58
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:18:01
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Timothy Hall (b) (4)	16 Oct 2020 17:00:11



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:18:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:18:05
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:18:08
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

US3682001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:18:11
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:18:13
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:18:15
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Oct 2020 17:03:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 17:03:01
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Timothy Hall (b) (4)	16 Oct 2020 17:03:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Oct 2020 17:00:11
User entered empty.	System	16 Oct 2020 17:00:11
	Timothy Hall (b) (4)	16 Oct 2020 17:00:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:18:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Oct 2020 17:03:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 17:03:01
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Timothy Hall (b) (4)	16 Oct 2020 17:03:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Oct 2020 17:00:11
User entered empty.	System	16 Oct 2020 17:00:11
	Timothy Hall (b) (4)	16 Oct 2020 17:00:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:08

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:18:21
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Oct 2020 17:03:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 17:03:01
User entered 'None (NONE)' reason for change: Data Entry Error	Timothy Hall (b) (4)	16 Oct 2020 17:03:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Oct 2020 17:00:11
User entered empty.	System	16 Oct 2020 17:00:11
	Timothy Hall (b) (4)	16 Oct 2020 17:00:11
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:18:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'l'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:18:30
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:18:34
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:18:35
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Timothy Hall (b) (4) (b) (4)	16 Oct 2020 17:00:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:18:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:18:37
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Timothy Hall (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:18:44
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Pt reports numbness in her L arm during sleep starting around 3:00 am, resolved without sequelae by 7:00.'	(b) (4) Timothy Hall (b) (4)	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
User entered '0'	System	16 Oct 2020 17:00:11

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39
User entered '0'	System	16 Oct 2020 17:00:11



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:39

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:21:48
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 13:21:04
User entered	System	03 Dec 2020 13:21:01
'USA-US081-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	03 Dec 2020 13:21:01

US3682001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:08

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:21:50
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 09:49:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 09:49:21
Data point term sent to Coder	System	02 Dec 2020 22:52:14
User entered 'Worsening of Osteoarthritis r knee'	Susan Reed (b) (4)	02 Dec 2020 22:52:01
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:42:58
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	02 Dec 2020 22:52:01

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:00
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	02 Dec 2020 22:52:01

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:04
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	02 Dec 2020 22:52:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:43:09
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 23:27:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Dec 2020 23:27:44
User entered '17 Sep 2020' reason for change: New Information	Susan Reed (b) (4)	02 Dec 2020 23:27:44
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 22:52:01
User entered empty.	Susan Reed (b) (4)	02 Dec 2020 22:52:01
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:19:04
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	02 Dec 2020 22:52:01
	(b) (4)	



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 22:52:01

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:11
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	02 Dec 2020 22:52:01

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:14
User entered '30 Nov 2020'	Susan Reed (b) (4) (b) (4)	02 Dec 2020 22:52:01

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:19:06
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	02 Dec 2020 22:52:01
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 22:52:01

US3682001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:08

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:43:15
User closed query 'PV Query: Please confirm the severity, since the event lead to hospitalization.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 19:45:22
Query 'PV Query: Please confirm the severity, since the event lead to hospitalization.' answered with 'Pt had a planned hospitalization. Severity updated to grade 4 due to this hospitalization.' (Site from Safety).	Mitchell Stern (b) (4)	16 Dec 2020 18:11:25
	(b) (4)	
User entered 'Grade 4 (Grade 4)' reason for change: Per Query Resolution	Mitchell Stern (b) (4)	16 Dec 2020 18:11:19
	(b) (4)	
User opened query 'PV Query: Please confirm the severity, since the event lead to hospitalization.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 15:01:46
User entered 'Grade 3/Severe (Grade 3/Severe)'	Susan Reed (b) (4)	02 Dec 2020 22:52:01
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:18
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	02 Dec 2020 22:52:01

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:19:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Susan Reed (b) (4)	02 Dec 2020 22:52:01
	(b) (4)	



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:19:19
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Susan Reed (b) (4)	02 Dec 2020 22:52:01
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:19:20
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Susan Reed (b) (4)	02 Dec 2020 22:52:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:20
User entered '30 Nov 2020'	Susan Reed (b) (4) (b) (4)	02 Dec 2020 22:52:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:08

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:43:22
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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 17:49:50
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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Emailed 12/9/2020 @ 16:27' (Site from Safety).	Susan Reed (b) (4)	10 Dec 2020 00:28:30
User entered '01 Dec 2020' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 00:28:23
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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:45:55
User entered '1 Dec 2020'	Susan Reed (b) (4)	02 Dec 2020 22:52:01
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:27
User entered 'No (N)'	Susan Reed (b) (4) (b) (4)	02 Dec 2020 22:52:01

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:19:24
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	02 Dec 2020 22:52:01
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:19:28
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Susan Reed (b) (4)	02 Dec 2020 22:52:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:19:35
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Susan Reed (b) (4)	02 Dec 2020 22:52:01
	(b) (4)	



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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:19:37
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Susan Reed (b) (4)	02 Dec 2020 22:52:01
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:29
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4) (b) (4)	02 Dec 2020 22:52:01

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:32
User entered 'Not Related (NOT RELATED)'	Susan Reed (b) (4) (b) (4)	02 Dec 2020 22:52:01

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Folder: Adverse Events

Form: Adverse Events (4)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:43:41
User closed query 'PV Query: The action taken with study drug should be 'No change' since the subject still had not received the second dose of study drug at the onset of the event. ' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:26:02
Query 'PV Query: The action taken with study drug should be 'No change' since the subject still had not received the second dose of study drug at the onset of the event. ' answered with 'updated appropriately. ' (Site from Safety).	Mitchell Stern (b) (4)	13 Jan 2021 21:05:23
	(b) (4)	
User entered 'None (NONE)' reason for change: Per Query Resolution	Mitchell Stern (b) (4)	13 Jan 2021 21:05:13
	(b) (4)	
User opened query 'PV Query: The action taken with study drug should be 'No change' since the subject still had not received the second dose of study drug at the onset of the event. ' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 19:54:48
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 16:03:55
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' answered with 'will evaluate at the time of OL visit. ' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 21:20:44
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 18:28:25
User closed query 'Per CDM: RQ: Response noted. Kindly consider to complete Dosing Discontinuation Form. Thank you ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 04:27:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:08

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per CDM: RQ: Response noted. Kindly consider to complete Dosing Discontinuation Form. Thank you ' answered with 'This was a planned surgery. Pt is recovering well. Withdrawal of IP is not applicable in this case.' (Site from DM).	Mitchell Stern (b) (4)	29 Dec 2020 17:32:31
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Mitchell Stern (b) (4)	29 Dec 2020 17:32:26
User opened query 'Per CDM: RQ: Response noted. Kindly consider to complete Dosing Discontinuation Form. Thank you ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 14:13:20
User closed query 'PV: PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 17:49:41
Query 'PV: PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'updated as requested' (Site from Safety).	Susan Reed (b) (4)	10 Dec 2020 00:29:06
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Susan Reed (b) (4)	10 Dec 2020 00:28:55
User opened query 'PV: PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:45:29
User entered 'Not Applicable (NOT APPLICABLE)'	Susan Reed (b) (4)	02 Dec 2020 22:52:01

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:19:44
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Susan Reed (b) (4)	02 Dec 2020 22:52:01
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:19:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Susan Reed (b) (4)	02 Dec 2020 22:52:01
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:19:53
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Susan Reed (b) (4)	02 Dec 2020 22:52:01
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:43:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Susan Reed (b) (4) (b) (4)	02 Dec 2020 22:52:01

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:01
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	02 Dec 2020 22:52:01
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:18:08

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:43:47
User closed query 'PV Query: Please provide the result of COVID-19 testing, if available/applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 18:21:00
Query 'PV Query: Please provide the result of COVID-19 testing, if available/applicable.' answered with 'COVID-19 testing and result was not in the requested hospital paperwork.' (Site from Safety).	Mitchell Stern (b) (4)	23 Dec 2020 00:23:34
User opened query 'PV Query: Please provide the result of COVID-19 testing, if available/applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:20:39
User closed query 'PV Query: Please provide any exams of COVID-19, if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 19:45:32
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed, used to diagnose and or monitor the event. Please include units and reference ranges if applicable. As testing was not denoted on the discharge summary/record.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 19:45:30
Query 'PV Query: Please provide any exams of COVID-19, if applicable.' answered with 'Medical record of what we received sent to Safety_Moderna@iqvia.com' (Site from Safety).	Susan Reed (b) (4)	16 Dec 2020 18:54:42
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed, used to diagnose and or monitor the event. Please include units and reference ranges if applicable. As testing was not denoted on the discharge summary/record.' answered with 'Medical record of what we received sent to Safety_Moderna@iqvia.com' (Site from Safety).	Susan Reed (b) (4)	16 Dec 2020 18:54:37
User opened query 'PV Query: Please provide any exams of COVID-19, if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 15:02:24

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:18:08

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results with dates performed, used to diagnose and or monitor the event. Please include units and reference ranges if applicable. As testing was not denoted on the discharge summary/record.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 15:01:18
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 17:49:59
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 17:49:29
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Discharge summary sent as requested' (Site from Safety).	Susan Reed (b) (4)	10 Dec 2020 00:29:56
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Concomitant Procedure ecrf completed, conmeds updated.' (Site from Safety).	Susan Reed (b) (4)	10 Dec 2020 00:29:38
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:46:24

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:44:51
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Dec 2020 22:55:52
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	02 Dec 2020 22:55:52
User entered 'Pt had a total r knee replacement. This was a planned surgery. Pt's medical records to be requested.' reason for change: New Information	Susan Reed (b) (4)	02 Dec 2020 22:55:52
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Dec 2020 22:52:01
User entered empty.	Susan Reed (b) (4)	02 Dec 2020 22:52:01

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**Form: Adverse Events (4)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Dec 2020 22:52:01

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Dec 2020 22:52:01

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Dec 2020 22:52:01



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:08

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:46
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Post procedural pain - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 20:52:13
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 20:52:13
	(b) (4)	
Data point term sent to Coder	System	07 Dec 2020 18:50:20
User entered 'Pain related to right total knee arthroplasty'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:59
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:06
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:11
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

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Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:21
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '1 Dec 2020'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:25
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 18:50:04

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:27
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	



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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:32
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:38
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 18:50:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:41
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:42
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:44
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:46
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:47
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	



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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:18:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:49
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:51
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:53
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:21:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:01
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:05
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:07
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:11
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:18:08

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications (#20 to 22, 26, 27) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 16:20:43
Query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications (#20 to 22, 26, 27) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated as requested ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 17:39:23
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 17:39:14
User opened query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications (#20 to 22, 26, 27) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 10:32:30
User entered '1'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:18:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:20
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 17:39:14
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:22
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:32
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

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**Folder: Adverse Events**

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**Generated On: 10 Jun 2021 09:18:08**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:38
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:39
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:50:04
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Dec 2020 18:50:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Dec 2020 18:50:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38

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Folder: Adverse Events

Form: Adverse Events (6)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:51
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Gastrointestinal and hepatobiliary procedural complications, PT: Procedural nausea, LLT: Procedural nausea - version MedDRA\\23.0.	Coder Import (b) (4)	11 Dec 2020 06:30:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Dec 2020 06:30:45
Data point term sent to Coder	System	07 Dec 2020 18:52:21
User entered 'Nausea secondary to right total knee arthroplasty and associated medications'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:18:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:05
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:16
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:19
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '07 Dec 2020'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:21
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
User entered empty.	System	07 Dec 2020 18:52:04

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:23
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Mitchell Stern (b) (4)	15 Jan 2021 18:49:23
User entered 'Yes (Y)'	(b) (4)	
	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04
	(b) (4)	

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**Form: Adverse Events (6)**

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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:28
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '21 Dec 2020' reason for change: New Information	(b) (4)	15 Jan 2021 18:49:23
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:30
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
User entered empty.	System	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:32
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:18:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:43
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:46
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

US3682001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:18:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:48
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:53
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

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Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:18:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:04
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:07
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:18:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

US3682001

Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:17
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:21
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:29
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:18:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:31
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:36
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Not Applicable (NOT APPLICABLE)'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:40
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'l'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:47
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:24:54
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) Mitchell Stern (b) (4) (b) (4)	15 Jan 2021 18:49:23
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mitchell Stern (b) (4) (b) (4)	07 Dec 2020 18:52:04

US3682001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:18:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:11
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
User entered '0'	System	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38
User entered 'I'	System	07 Dec 2020 18:52:04

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:19:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32

US3682001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:18:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:19
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Gastrointestinal and hepatobiliary procedural complications, PT: Post procedural constipation, LLT: Post procedural constipation - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 19:21:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 19:21:59
Data point term sent to Coder	System	07 Dec 2020 18:54:22
User entered 'Constipation secondary to right total knee arthroplasty and associated medications'	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:28
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:33
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:35
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

US3682001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:42
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	07 Dec 2020 18:54:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 18:54:16
User entered '02 Dec 2020' reason for change: Data Entry Error	Mitchell Stern (b) (4)	07 Dec 2020 18:54:16
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	07 Dec 2020 18:53:38
User entered empty.	System	07 Dec 2020 18:53:38
	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:44
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
User entered empty.	System	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:47
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	07 Dec 2020 18:54:16
	(b) (4)	
	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38
	(b) (4)	

US3682001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	07 Dec 2020 18:54:16
User entered '03 Dec 2020' reason for change: Data Entry Error	Mitchell Stern (b) (4)	07 Dec 2020 18:54:16
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	07 Dec 2020 18:53:38
	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38
	(b) (4)	



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:58
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
User entered empty.	System	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38
	(b) (4)	

US3682001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:18:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:07
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:08
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:12
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:15
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:21
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:30
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

US3682001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:18:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:34
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:40
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38
	(b) (4)	

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:44
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:47
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:53
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:57
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:27:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38
	(b) (4)	

US3682001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:18:08

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:27:07
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#23) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4)	15 Jan 2021 16:21:07
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#23) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated as requested' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 17:40:19
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 17:40:11
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#23) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 10:32:47
User entered '1'	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:27:14
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 17:40:11
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:27:16
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:27:20
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:27:22
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:27:24
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
User entered '0'	System	07 Dec 2020 18:53:38



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32
User entered 'I'	System	07 Dec 2020 18:53:38

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:32

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39

US3682001

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:18:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:23
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 18:08:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 18:08:34
Data point term sent to Coder	System	09 Feb 2021 18:07:33
User entered 'headache'	(b) (4), (b) (6)	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:25
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	(b) (4), (b) (6)	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:30
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 18:06:44

US3682001

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:18:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:31
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	(b) (4), (b) (6)	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:38
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '18 Sep 2020'	(b) (4), (b) (6)	09 Feb 2021 18:06:44



US3682001

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:18:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:41
User closed query 'Per CDM:Kindly confirm in query response if the AE started before or after the dosing.Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 10:56:04
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
Query 'Per CDM:Kindly confirm in query response if the AE started before or after the dosing.Thank you.' answered with 'Headache began after dosing.' (Site from DM).	Jesse Clark (b) (4)	11 Feb 2021 22:14:20
User opened query 'Per CDM:Kindly confirm in query response if the AE started before or after the dosing.Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 03:14:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Feb 2021 03:14:02
Query 'Data is required. Please provide.' answered with 'start time is unk ' (Site from System).	(b) (4), (b) (6)	09 Feb 2021 18:06:51
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Feb 2021 18:06:44
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
User entered empty.	System	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:47
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	(b) (4), (b) (6)	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	09 Feb 2021 18:07:14
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	09 Feb 2021 18:07:14
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	09 Feb 2021 18:06:44
User entered '25 Sep 2020'	(b) (4), (b) (6)	09 Feb 2021 18:06:44

US3682001

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:18:08

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:52
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Feb 2021 03:15:09
Query 'Data is required. Please provide.' answered with 'end time is unk ' (Site from System).	(b) (4), (b) (6)	09 Feb 2021 18:07:24
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Feb 2021 18:06:44
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
User entered empty.	System	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	09 Feb 2021 18:06:44

US3682001

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:18:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:28:58
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'No (N)'	(b) (4), (b) (6)	09 Feb 2021 18:06:44



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:01
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:05
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 18:06:44

US3682001

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:18:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:07
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 18:06:44

US3682001

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:18:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:11
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:14
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 18:06:44



**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:19
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:22
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 18:06:44

US3682001

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:18:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:24
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Feb 2021 18:06:44

US3682001

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:18:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:27
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:31
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'None (NONE)'	(b) (4), (b) (6)	09 Feb 2021 18:06:44

US3682001

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:18:08

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:33
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	09 Feb 2021 18:08:03
User entered '1' reason for change: Data Entry Error	System	09 Feb 2021 18:08:03
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4), (b) (6)	09 Feb 2021 18:06:44
User entered '0'	System	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:35
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:38
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 18:06:44



US3682001

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:18:08

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:43
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	09 Feb 2021 18:07:14
Data Entry Error	(b) (4), (b) (6)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:45
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:47
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
User entered '0'	System	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39
User entered '0'	System	09 Feb 2021 18:06:44

**US3682001**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:18:39

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:18:08

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:13:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Per CDM: Re-query: Response noted. Kindly review and confirm the conmed log line number taken to treat pain or fever for Day 7 Diary dose.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:28:04
Query 'Per CDM: Re-query: Response noted. Kindly review and confirm the conmed log line number taken to treat pain or fever for Day 7 Diary dose.' answered with 'Line 16 and 17' (Site from DM).	Susan Reed (b) (4) (b) (4)	08 Sep 2020 19:01:52
User opened query 'Per CDM: Re-query: Response noted. Kindly review and confirm the conmed log line number taken to treat pain or fever for Day 7 Diary dose.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 11:55:10
User closed query 'Per CDM: Per the participant response, medication was taken to treat pain or fever for Day 7 Diary dose, however please confirm the participant was contacted to determine the medication details and record the medication on the concomitant medication pages. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 11:55:10
Query 'Per CDM: Per the participant response, medication was taken to treat pain or fever for Day 7 Diary dose, however please confirm the participant was contacted to determine the medication details and record the medication on the concomitant medication pages. Thank you' answered with 'Pt was contacted, medication has been entered on the concomitant medication page.' (Site from DM).	Susan Reed (b) (4) (b) (4)	02 Sep 2020 18:13:45
User opened query 'Per CDM: Per the participant response, medication was taken to treat pain or fever for Day 7 Diary dose, however please confirm the participant was contacted to determine the medication details and record the medication on the concomitant medication pages. Thank you' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 13:06:51

US3682001

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 09:18:08**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:53:45



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:08

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:30:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Per DM CLR: Please review and remove the dose information as this were already recorded in the appropriate fields within this eCRF. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:24:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BECLOMETASONE DIPROPIONATE, PRODUCTSYNONYM: QVAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 21:04:25
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 21:04:25
Data point term sent to Coder	System	06 Oct 2020 21:03:19
Query 'Per DM CLR: Please review and remove the dose information as this were already recorded in the appropriate fields within this eCRF. Review and update eCRF as appropriate. ' answered with 'form updated' (Site from DM).	Susan Reed (b) (4) (b) (4)	06 Oct 2020 21:03:05
Coding entries removed.	Susan Reed (b) (4) (b) (4)	06 Oct 2020 21:02:58
User entered 'QVAR INHALER' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	06 Oct 2020 21:02:58
User opened query 'Per DM CLR: Please review and remove the dose information as this were already recorded in the appropriate fields within this eCRF. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 01:45:18

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BECLOMETASONE DIPROPIONATE, PRODUCTSYNONYM: QVAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 05:23:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 05:23:27
Data point term sent to Coder	System	21 Aug 2020 18:56:40
User entered 'Qvar inhaler 40 mcg 1 puff BID'	Timothy Hall (b) (4)	21 Aug 2020 18:55:41

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:30:57
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Timothy Hall (b) (4)	21 Aug 2020 18:55:41
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:31:00
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'asthma'	Timothy Hall (b) (4)	21 Aug 2020 18:55:41
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:31:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '40'	Timothy Hall (b) (4)	21 Aug 2020 18:55:41
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'This is mcg in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:06:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:05:59
Query 'This is mcg in source document. Please verify and update accordingly.' answered with 'Updated accordingly' (Site from CRA).	Mitchell Stern (b) (4)	16 Apr 2021 21:30:42
User opened query 'This is mcg in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4)	16 Apr 2021 19:32:10
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 19:31:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:31:04
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'ug (ug)'	Timothy Hall (b) (4)	21 Aug 2020 18:55:41

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:14
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:55:41
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'twice daily (BID)'	Timothy Hall (b) (4)	21 Aug 2020 18:55:41
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:22
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:55:41
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:27
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Timothy Hall (b) (4)	21 Aug 2020 18:55:41
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:18:08**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:31
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:55:41
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:34
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'UN UNK 2010'	Timothy Hall (b) (4)	21 Aug 2020 18:55:41
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:37
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Timothy Hall (b) (4)	21 Aug 2020 18:55:41
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:40
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 18:55:41
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:42
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:55:41
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:46
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Timothy Hall (b) (4)	21 Aug 2020 19:15:16
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 18:55:41
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 18:55:41

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:55:41

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 18:55:41

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:52
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: LEVOSALBUTAMOL HYDROCHLORIDE, PRODUCTSYNONYM: XOPENEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 03:45:24
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 03:45:24
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 18:57:48
User entered 'Xopenex inhaler'	Timothy Hall (b) (4)	21 Aug 2020 18:57:42
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Timothy Hall (b) (4)	21 Aug 2020 18:57:42
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:58
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'asthma exacerbation'	Timothy Hall (b) (4)	21 Aug 2020 18:57:42
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:01
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '45'	Timothy Hall (b) (4)	21 Aug 2020 18:57:42
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'This is mcg in source document. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:08:19
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:08:16
Query 'This is mcg in source document. Please verify and update accordingly. ' answered with 'Updated accordingly' (Site from CRA).	Mitchell Stern (b) (4) (b) (4)	16 Apr 2021 21:31:35
User opened query 'This is mcg in source document. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:33:25
User signature succeeded.	Jesse Clark (b) (4) (b) (4)	12 Feb 2021 17:57:35
User entered 'ug (ug)'	Timothy Hall (b) (4) (b) (4)	21 Aug 2020 18:57:42



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:18:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:28
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:57:42
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:32
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'as needed (PRN)'	Timothy Hall (b) (4)	21 Aug 2020 18:57:42
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:34
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:57:42
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:37
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Timothy Hall (b) (4)	21 Aug 2020 18:57:42
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:18:08**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:39
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:57:42
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:41
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	21 Aug 2020 19:12:59
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	21 Aug 2020 19:12:02
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 19:12:02
User entered empty; reason for change Data Entry Error	Timothy Hall (b) (4)	21 Aug 2020 19:12:02
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 18:57:42
User entered 'UN UNK UNKN' (non-conformant).	Timothy Hall (b) (4)	21 Aug 2020 18:57:42
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:18:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:44
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Timothy Hall (b) (4)	21 Aug 2020 19:12:59
	(b) (4)	
Comment added 'data entry error'.	Timothy Hall (b) (4)	21 Aug 2020 19:12:28
	(b) (4)	
User entered '0'	Timothy Hall (b) (4)	21 Aug 2020 18:57:42
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:46
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 18:57:42
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:18:08**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:48
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:57:42
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:51
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Timothy Hall (b) (4)	21 Aug 2020 18:57:42
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:57:42

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:57:42

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:57:42

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:57
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 19:01:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 19:01:21
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 18:59:56
User entered 'multivitamin'	Timothy Hall (b) (4)	21 Aug 2020 18:59:09
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 18:59:09
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:14
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'general health'	Timothy Hall (b) (4)	21 Aug 2020 18:59:09
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:17
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Timothy Hall (b) (4)	21 Aug 2020 18:59:09
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:19
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'tablet (TABLET)'	Timothy Hall (b) (4)	21 Aug 2020 18:59:09
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:18:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:21
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:59:09
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:23
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'once daily (QD)'	Timothy Hall (b) (4)	21 Aug 2020 18:59:09
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:25
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:59:09
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Timothy Hall (b) (4)	21 Aug 2020 18:59:09
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:18:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:28
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:59:09
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:33
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:59:09
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:35
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Timothy Hall (b) (4)	21 Aug 2020 18:59:09
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:38
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 18:59:09
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:39
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:59:09
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:41
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Timothy Hall (b) (4)	21 Aug 2020 18:59:09
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:59:09

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:59:09

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 18:59:09

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:08

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:52
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 13:18:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 13:18:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 20:50:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 20:50:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 20:54:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 20:54:51



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 13:30:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 13:30:42
Data point term sent to Coder	System	21 Aug 2020 18:59:58
User entered 'B complex vitamin'	Timothy Hall (b) (4)	21 Aug 2020 18:59:41

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 18:59:41
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'general health'	Timothy Hall (b) (4)	21 Aug 2020 18:59:41
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:07
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Timothy Hall (b) (4)	21 Aug 2020 18:59:41
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:12
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'tablet (TABLET)'	Timothy Hall (b) (4)	21 Aug 2020 18:59:41
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:15
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:59:41
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:20
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'once daily (QD)'	Timothy Hall (b) (4)	21 Aug 2020 18:59:41
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:22
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:59:41
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:24
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Timothy Hall (b) (4)	21 Aug 2020 18:59:41
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:42
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:59:41
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:44
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:59:41
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:06
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Timothy Hall (b) (4)	21 Aug 2020 18:59:41
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:07
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 18:59:41
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:18:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 18:59:41
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Timothy Hall (b) (4)	21 Aug 2020 18:59:41
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:59:41



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:59:41

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 18:59:41

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:32
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
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: D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 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)	21 Aug 2020 19:01:23
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 19:00:59
User entered 'D3'	Timothy Hall (b) (4)	21 Aug 2020 19:00:12
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:34
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:00:12
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:39
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'general health'	Timothy Hall (b) (4)	21 Aug 2020 19:00:12
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:43
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '2000'	Timothy Hall (b) (4)	21 Aug 2020 19:00:12
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:56
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'IU (IU)'	Timothy Hall (b) (4)	21 Aug 2020 19:00:12
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:18:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:20
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:00:12
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:23
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'once daily (QD)'	Timothy Hall (b) (4)	21 Aug 2020 19:00:12
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:08

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:25
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:00:12
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Timothy Hall (b) (4)	21 Aug 2020 19:00:12
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:28
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:00:12
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:30
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:00:12
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:31
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Timothy Hall (b) (4)	21 Aug 2020 19:00:12
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:33
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:00:12
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:18:08**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:35
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:00:12
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:36
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Timothy Hall (b) (4)	21 Aug 2020 19:00:12
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:00:12

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:00:12

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 19:00:12

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:41
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 05:29:28
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 05:29:28
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 19:00:59
User entered 'probiotic supplement'	Timothy Hall (b) (4)	21 Aug 2020 19:00:43
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:42
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:00:43
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:44
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'general health'	Timothy Hall (b) (4)	21 Aug 2020 19:00:43
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:46
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Timothy Hall (b) (4)	21 Aug 2020 19:00:43
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:48
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'capsule (CAPSULE)'	Timothy Hall (b) (4)	21 Aug 2020 19:00:43
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:00:43
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:51
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'once daily (QD)'	Timothy Hall (b) (4)	21 Aug 2020 19:00:43
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:53
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:00:43
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Timothy Hall (b) (4)	21 Aug 2020 19:00:43
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:18:08**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:58
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:00:43
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:00
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:00:43
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:01
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Timothy Hall (b) (4)	21 Aug 2020 19:00:43
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:00:43
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:18:08**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:08
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:00:43
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Timothy Hall (b) (4)	21 Aug 2020 19:00:43
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:00:43

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:00:43

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 19:00:43

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:17
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COENZYME Q10 [UBIDECARENONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Aug 2020 19:16:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 19:14:42
Data point term sent to Coder	System	21 Aug 2020 19:04:05
User entered 'Coenzyme Q10'	Timothy Hall (b) (4)	21 Aug 2020 19:03:29
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:20
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:03:29
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:25
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'General health' reason for change:	Timothy Hall (b) (4)	21 Aug 2020 19:14:14
Data Entry Error	(b) (4)	
User entered 'generla'	Timothy Hall (b) (4)	21 Aug 2020 19:03:29
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:28
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:15:29
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'confirmed with pt' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:15:35
User entered '100' reason for change: Per Query Resolution	Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:15:08
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 01:54:10
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 19:14:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 19:14:14
User entered '1' reason for change: Data Entry Error	Timothy Hall (b) (4) (b) (4)	21 Aug 2020 19:14:14
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 19:03:29
User entered empty.	Timothy Hall (b) (4) (b) (4)	21 Aug 2020 19:03:29

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:33
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'mg (mg)' reason for change: Per Query Resolution	Susan Reed (b) (4)	09 Oct 2020 16:15:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 19:14:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 19:14:14
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Timothy Hall (b) (4)	21 Aug 2020 19:14:14
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 19:03:29
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:03:29
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:35
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:03:29
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:37
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 19:14:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 19:14:14
User entered 'once daily (QD)' reason for change: Data Entry Error	Timothy Hall (b) (4)	21 Aug 2020 19:14:14
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 19:03:29
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:03:29
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:39
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:03:29
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:41
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 19:14:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 19:14:14
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Timothy Hall (b) (4)	21 Aug 2020 19:14:14
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 19:03:29
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:03:29
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:03:29
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:29
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:03:29
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:30
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'l'	Timothy Hall (b) (4)	21 Aug 2020 19:03:29
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:34
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Susan Reed (b) (4)	09 Oct 2020 16:15:08
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:03:29
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:14
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '5 Oct 2020' reason for change: New Information	Susan Reed (b) (4)	09 Oct 2020 16:15:08
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:03:29
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:16
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Timothy Hall (b) (4)	21 Aug 2020 19:03:29
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
User entered '1'	System	21 Aug 2020 19:14:14
User entered empty.	System	21 Aug 2020 19:03:29

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
User entered '1'	System	21 Aug 2020 19:14:14
User entered empty.	System	21 Aug 2020 19:03:29

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:38
User entered '804 (804)'	System	21 Aug 2020 19:14:14
User entered empty.	System	21 Aug 2020 19:03:29



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:28
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM GLYCINATE, PRODUCTSYNONYM: MAGNESIUM BISGLYCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 19:05:17
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 19:05:17
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 19:05:07
User entered 'magnesium bisglycinate'	Timothy Hall (b) (4)	21 Aug 2020 19:04:11
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:31
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:04:11
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:37
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'general health'	Timothy Hall (b) (4)	21 Aug 2020 19:04:11
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:39
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '200'	Timothy Hall (b) (4)	21 Aug 2020 19:04:11
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:40
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'mg (mg)'	Timothy Hall (b) (4)	21 Aug 2020 19:04:11
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:18:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:43
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:04:11
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:45
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'once daily (QD)'	Timothy Hall (b) (4)	21 Aug 2020 19:04:11
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:47
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:04:11
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:52
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Timothy Hall (b) (4)	21 Aug 2020 19:04:11
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:54
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:04:11
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:56
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:04:11
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:57
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Timothy Hall (b) (4)	21 Aug 2020 19:04:11
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:04:11
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:18:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:04
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:04:11
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:06
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Timothy Hall (b) (4)	21 Aug 2020 19:04:11
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:04:11



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:04:11

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 19:04:11

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:13
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS, PRODUCT: MONASCUS PURPUREUS, PRODUCTSYNONYM: RED RICE YEAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 19:16:21
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	21 Aug 2020 19:16:21
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 19:15:48
Data point term sent to Coder	System	21 Aug 2020 19:06:15
User entered 'red yeast rice'	Timothy Hall (b) (4)	21 Aug 2020 19:05:33
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:14
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Per DM CLR: Prophylaxis = YES. Please note this medication is not given as a prophylaxis. It is used to treat a condition or as a health supplement. Review and either remove the prophylaxis indication and add a condition to the Med History eCRF to match this medication or clarify the recorded indication.'	(b) (4), (b) (6)	07 Oct 2020 19:11:07
(Site from DM).		
Query 'Per DM CLR: Prophylaxis = YES. Please note this medication is not given as a prophylaxis. It is used to treat a condition or as a health supplement. Review and either remove the prophylaxis indication and add a condition to the Med History eCRF to match this medication or clarify the recorded indication.'	Susan Reed (b) (4)	06 Oct 2020 21:04:05
' answered with 'form updated' (Site from DM).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Susan Reed (b) (4)	06 Oct 2020 21:03:57
User opened query 'Per DM CLR: Prophylaxis = YES. Please note this medication is not given as a prophylaxis. It is used to treat a condition or as a health supplement. Review and either remove the prophylaxis indication and add a condition to the Med History eCRF to match this medication or clarify the recorded indication.'	(b) (4), (b) (6)	05 Oct 2020 01:54:54
(Site from DM).		
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:05:33
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:30
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 19:14:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 19:14:56
User entered 'hyperlipidemia' reason for change:	Timothy Hall (b) (4)	21 Aug 2020 19:14:56
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 19:05:33
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:05:33
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:37
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '1000'	Timothy Hall (b) (4)	21 Aug 2020 19:05:33
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:42
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'mg (mg)'	Timothy Hall (b) (4)	21 Aug 2020 19:05:33
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:46
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:05:33
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:57
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'once daily (QD)'	Timothy Hall (b) (4)	21 Aug 2020 19:05:33
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:18:08

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:59
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:05:33
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Timothy Hall (b) (4)	21 Aug 2020 19:05:33
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:18:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:05
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:05:33
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:06
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:05:33
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Timothy Hall (b) (4)	21 Aug 2020 19:05:33
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:11
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:05:33
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:18:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:16
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:05:33
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:17
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Timothy Hall (b) (4)	21 Aug 2020 19:05:33
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:05:33

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:05:33

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 19:05:33

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:24
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: NICOTINIC ACID AND DERIVATIVES, PRODUCT: NICOTINIC ACID, PRODUCTSYNONYM: NIACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 19:08:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 19:08:23
	(b) (4)	
Data point term sent to Coder User entered 'niacin'	System	21 Aug 2020 19:07:19
	Timothy Hall (b) (4)	21 Aug 2020 19:06:44
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:27
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Per DM CLR: Prophylaxis = YES. Please note this medication is not given as a prophylaxis. It is used to treat a condition or as a health supplement. Review and either remove the prophylaxis indication and add a condition to the Med History eCRF to match this medication or clarify the recorded indication.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 07:09:58
Query 'Per DM CLR: Prophylaxis = YES. Please note this medication is not given as a prophylaxis. It is used to treat a condition or as a health supplement. Review and either remove the prophylaxis indication and add a condition to the Med History eCRF to match this medication or clarify the recorded indication.' answered with 'update complete' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:27:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 19:26:58
User opened query 'Per DM CLR: Prophylaxis = YES. Please note this medication is not given as a prophylaxis. It is used to treat a condition or as a health supplement. Review and either remove the prophylaxis indication and add a condition to the Med History eCRF to match this medication or clarify the recorded indication.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 01:52:03
Query 'Per DM CLR: Prophylaxis = YES. Please note this medication is not given as a prophylaxis. It is used to treat a condition. Review and either remove the prophylaxis indication and add a condition to the Med History eCRF to match this medication or clarify the recorded indication.' canceled (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 01:51:59

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Prophylaxis = YES. Please note this medication is not given as a prophylaxis. It is used to treat a condition. Review and either remove the prophylaxis indication and add a condition to the Med History eCRF to match this medication or clarify the recorded indication.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 01:45:33
User entered 'Yes (Y)'	Timothy Hall (b) (4) (b) (4)	21 Aug 2020 19:06:44

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:33
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 07:10:34
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'update complete' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:27:11
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 01:45:47
User entered 'hyperlipidemia'	Timothy Hall (b) (4)	21 Aug 2020 19:06:44
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:42
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '500'	Timothy Hall (b) (4)	21 Aug 2020 19:06:44
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:43
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'mg (mg)'	Timothy Hall (b) (4)	21 Aug 2020 19:06:44
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:45
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:06:44
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:48
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'once daily (QD)'	Timothy Hall (b) (4)	21 Aug 2020 19:06:44
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:18:08

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:51
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:06:44
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:58
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Timothy Hall (b) (4)	21 Aug 2020 19:06:44
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:00
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:06:44
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:06:44
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:18:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:07
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Timothy Hall (b) (4)	21 Aug 2020 19:06:44
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:19
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:06:44
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:21
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:06:44
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:23
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Timothy Hall (b) (4)	21 Aug 2020 19:06:44
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:06:44

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:06:44

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 19:06:44

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:28
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: OMEGA-3 FATTY ACIDS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 12:26:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 12:26:50
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 19:08:20
User entered 'omega 3 fatty acids'	Timothy Hall (b) (4)	21 Aug 2020 19:07:22
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:36
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User closed query 'Per DM CLR: Prophylaxis = YES. Please note this medication is not given as a prophylaxis. It is used to treat a condition or as a health supplement. Review and either remove the prophylaxis indication and add a condition to the Med History eCRF to match this medication or clarify the recorded indication.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 18:04:58
Query 'Per DM CLR: Prophylaxis = YES. Please note this medication is not given as a prophylaxis. It is used to treat a condition or as a health supplement. Review and either remove the prophylaxis indication and add a condition to the Med History eCRF to match this medication or clarify the recorded indication.' answered with 'form updated' (Site from DM).	Susan Reed (b) (4)	09 Oct 2020 16:20:54
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Susan Reed (b) (4)	09 Oct 2020 16:20:47
	(b) (4)	
User opened query 'Per DM CLR: Prophylaxis = YES. Please note this medication is not given as a prophylaxis. It is used to treat a condition or as a health supplement. Review and either remove the prophylaxis indication and add a condition to the Med History eCRF to match this medication or clarify the recorded indication.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 01:52:11
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:07:22
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:18:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:40
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'hyperlipidemia'	Timothy Hall (b) (4)	21 Aug 2020 19:07:22
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:43
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '1280'	Timothy Hall (b) (4)	21 Aug 2020 19:07:22
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:45
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'mg (mg)'	Timothy Hall (b) (4)	21 Aug 2020 19:07:22
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:18:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:47
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:07:22
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:18:08**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:52
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'every other day (QOD)'	Timothy Hall (b) (4)	21 Aug 2020 19:07:22
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:57
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:07:22
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:43:59
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Timothy Hall (b) (4)	21 Aug 2020 19:07:22
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:07:22
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:05
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:07:22
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:18:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:07
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Timothy Hall (b) (4)	21 Aug 2020 19:07:22
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:07:22
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:18:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:07:22
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:18:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:19
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Timothy Hall (b) (4)	21 Aug 2020 19:07:22
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:07:22

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 19:07:22



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 19:07:22

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:23
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: HERBAL PREPARATION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 09:36:49
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 09:36:49
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 19:08:23
User entered 'liver support blend - NAC and milk thistle extract'	Timothy Hall (b) (4)	21 Aug 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:27
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:05:19
Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' answered with 'form updated' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:21:22
User entered 'No (N)' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:21:15
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 01:52:43
User entered 'Yes (Y)'	Timothy Hall (b) (4) (b) (4)	21 Aug 2020 19:08:05

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:18:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:30
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'early steatohepatitis'	Timothy Hall (b) (4)	21 Aug 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:18:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:34
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Timothy Hall (b) (4)	21 Aug 2020 19:08:05
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:36
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'capsule (CAPSULE)'	Timothy Hall (b) (4)	21 Aug 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:38
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:40
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'once daily (QD)'	Timothy Hall (b) (4)	21 Aug 2020 19:08:05
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:42
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:08:05
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:45
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Timothy Hall (b) (4)	21 Aug 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:46
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:51
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:18:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Timothy Hall (b) (4)	21 Aug 2020 19:08:05
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:57
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:59
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:45:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Timothy Hall (b) (4)	21 Aug 2020 19:08:05
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:08:05

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:08:05

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 19:08:05

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:18:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:45:12
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: GLUTATHIONE;PHOSPHATIDYL CHOLINE, PRODUCTSYNONYM: LIPOSOMAL GLUTATHIONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 19:10:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 19:10:27
Data point term sent to Coder	System	21 Aug 2020 19:09:26
User entered 'liposomal glutathione'	Timothy Hall (b) (4) (b) (4)	21 Aug 2020 19:08:42

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:45:14
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 09:17:18
User entered 'No (N)' reason for change: Data Entry Error	Oladunni Adeyiga (b) (4)	14 Oct 2020 18:29:04
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4)	09 Oct 2020 16:21:44
User entered 'Yes (Y)'	Susan Reed (b) (4)	05 Oct 2020 01:52:54
	(b) (4), (b) (6)	21 Aug 2020 19:08:42

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:45:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'early steatohepatitis'	Timothy Hall (b) (4)	21 Aug 2020 19:08:42
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:18:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:45:42
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of capsule/s as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 09:17:26
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of capsule/s as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	Oladunni Adeyiga (b) (4)	14 Oct 2020 18:29:13
User entered '100' reason for change: Data Entry Error	Oladunni Adeyiga (b) (4)	14 Oct 2020 18:28:56
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of capsule/s as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 01:53:03
User entered '1'	Timothy Hall (b) (4)	21 Aug 2020 19:08:42

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:45:46
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Oladunni Adeyiga (b) (4)	14 Oct 2020 18:28:56
	(b) (4)	
User entered 'capsule (CAPSULE)'	Timothy Hall (b) (4)	21 Aug 2020 19:08:42
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:45:54
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:08:42
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:45:56
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'once daily (QD)'	Timothy Hall (b) (4)	21 Aug 2020 19:08:42
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:18:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:45:58
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:08:42
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:18:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:46:01
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Timothy Hall (b) (4)	21 Aug 2020 19:08:42
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:46:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:08:42
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:46:04
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:08:42
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:18:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:46:06
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'l'	Timothy Hall (b) (4)	21 Aug 2020 19:08:42
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:18:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:46:08
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Timothy Hall (b) (4)	18 Sep 2020 17:10:17
	(b) (4)	
Comment added 'stopped on 09/04/2020'.	Timothy Hall (b) (4)	18 Sep 2020 17:09:45
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:08:42
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:46:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	18 Sep 2020 17:10:17
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	18 Sep 2020 17:10:05
User entered '4 Sep 2020' reason for change: New Information	Timothy Hall (b) (4)	18 Sep 2020 17:10:05
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:08:42
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:46:12
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Timothy Hall (b) (4)	21 Aug 2020 19:08:42
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
User entered '1'	System	21 Aug 2020 19:08:42

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
User entered '1'	System	21 Aug 2020 19:08:42

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:45
User entered '804 (804)'	System	21 Aug 2020 19:08:42

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:46:20
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 19:10:26
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 19:10:26
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 19:09:26
User entered 'calcium'	Timothy Hall (b) (4)	21 Aug 2020 19:09:16
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:46:22
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 18:05:46
Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'form updated' (Site from DM).	Susan Reed (b) (4)	09 Oct 2020 16:22:18
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Susan Reed (b) (4)	09 Oct 2020 16:22:06
	(b) (4)	
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 01:53:17
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:09:16
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:15:12
User closed query 'This is stated as GH per source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 23:14:59
Query 'This is stated as GH per source document. Please verify and update accordingly.' answered with 'Updated accordingly' (Site from CRA).	Mitchell Stern (b) (4)	16 Apr 2021 21:37:06
	(b) (4)	
User opened query 'This is stated as GH per source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:47:08
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 19:46:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:46:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'osteoarthritis'	Timothy Hall (b) (4)	21 Aug 2020 19:09:16
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:18:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:21
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '500'	Timothy Hall (b) (4)	21 Aug 2020 19:09:16
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:23
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'mg (mg)'	Timothy Hall (b) (4)	21 Aug 2020 19:09:16
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:15
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:09:16
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'once daily (QD)'	Timothy Hall (b) (4)	21 Aug 2020 19:09:16
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:29
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:09:16
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:31
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Timothy Hall (b) (4)	21 Aug 2020 19:09:16
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:34
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:09:16
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:36
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:09:16
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:43
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Timothy Hall (b) (4)	21 Aug 2020 19:09:16
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:44
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:09:16
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:18:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:46
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:09:16
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Timothy Hall (b) (4)	21 Aug 2020 19:09:16
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:09:16

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:09:16

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 19:09:16

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:18:08

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:47:56
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 17:59:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 17:59:47
Data point term sent to Coder	System	28 Aug 2020 18:16:10
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	28 Aug 2020 18:15:56
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'Spelling correct, active ingredients put in parentheses.' (Site from System).	Susan Reed (b) (4)	28 Aug 2020 18:15:56
User entered 'IMMUCORE MULTIVITAMIN SUPPLEMENT(Vitamin D, Vitamin C, Niacin, Zinc, Selenium)' reason for change: Data Entry Error	Susan Reed (b) (4)	28 Aug 2020 18:15:10
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	26 Aug 2020 08:21:36
Data point term sent to Coder	System	21 Aug 2020 19:10:29

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Immucore multivitamin supplement'	Timothy Hall (b) (4) (b) (4)	21 Aug 2020 19:10:02

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:10:02
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:18:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:06
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'general health'	Timothy Hall (b) (4)	21 Aug 2020 19:10:02
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:11
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Timothy Hall (b) (4)	21 Aug 2020 19:10:02
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:21
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'tablet (TABLET)'	Timothy Hall (b) (4)	21 Aug 2020 19:10:02
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:18:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:24
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:10:02
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:18:08**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:27
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'once daily (QD)'	Timothy Hall (b) (4)	21 Aug 2020 19:10:02
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:30
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:10:02
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:32
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Timothy Hall (b) (4)	21 Aug 2020 19:10:02
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:35
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:10:02
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:37
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:10:02
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:39
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'I'	Timothy Hall (b) (4)	21 Aug 2020 19:10:02
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:41
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Timothy Hall (b) (4)	21 Aug 2020 19:10:02
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:49
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Timothy Hall (b) (4)	21 Aug 2020 19:10:02
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:48:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Timothy Hall (b) (4)	21 Aug 2020 19:10:02
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:10:02



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:10:02

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 19:10:02

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:18:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:49:01
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Aug 2020 17:29:48
User coded data point as Term Coded data point by	Coder Import (b) (4)	28 Aug 2020 17:29:48
User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 17:28:45
User entered 'Aleve'	Susan Reed (b) (4) (b) (4)	28 Aug 2020 17:27:58

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:49:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Susan Reed (b) (4)	28 Aug 2020 17:27:58
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:49:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 09:16:17
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'solicited event within 7 day window' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:19:53

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM). User entered 'Headache'	(b) (4), (b) (6) Susan Reed (b) (4) (b) (4)	05 Oct 2020 01:53:42 28 Aug 2020 17:27:58

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:18:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:49:19
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '220' reason for change: Per Query Resolution	Mitchell Stern (b) (4)	07 Dec 2020 18:59:17
	(b) (4)	
User entered 'I'	Susan Reed (b) (4)	28 Aug 2020 17:27:58
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:49:23
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 250 MG, 500 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 250 MG, 500 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated per query resolution' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 11:45:05
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 250 MG, 500 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated per query resolution' (Site from DM).	Mitchell Stern (b) (4)	07 Dec 2020 18:59:30
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4)	07 Dec 2020 18:59:17
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 250 MG, 500 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 14:23:05
User entered 'tablet (TABLET)'	Susan Reed (b) (4)	28 Aug 2020 17:27:58
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:49:25
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	28 Aug 2020 17:27:58
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:49:35
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'as needed (PRN)' reason for change:	Susan Reed (b) (4)	25 Sep 2020 17:17:36
Data Entry Error	(b) (4)	
User entered 'once (ONCE)'	Susan Reed (b) (4)	28 Aug 2020 17:27:58
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:49:37
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	28 Aug 2020 17:27:58
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:49:41
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Susan Reed (b) (4)	28 Aug 2020 17:27:58
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:49:44
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	28 Aug 2020 17:27:58
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:49:48
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '25 Aug 2020' reason for change: Data Entry Error	Susan Reed (b) (4)	04 Nov 2020 19:36:55
	(b) (4)	
User entered empty; reason for change Data Entry Error	Susan Reed (b) (4)	04 Nov 2020 19:08:48
	(b) (4)	
User entered '25 Aug 2020'	Susan Reed (b) (4)	28 Aug 2020 17:27:58
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:18:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:21
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Susan Reed (b) (4)	04 Nov 2020 19:36:55
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Susan Reed (b) (4)	04 Nov 2020 19:08:48
	(b) (4)	
User entered '0'	Susan Reed (b) (4)	28 Aug 2020 17:27:58
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:18:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:19
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User closed query 'Per DM CLR: Please confirm if this medication is still ongoing as the noted solicited adverse reaction has already resolved in the Diary card. Reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 06:56:56
Query 'Per DM CLR: Please confirm if this medication is still ongoing as the noted solicited adverse reaction has already resolved in the Diary card. Reconcile and update as appropriate, otherwise clarify.' answered with 'data corrected' (Site from DM).	Susan Reed (b) (4)	04 Nov 2020 19:37:06
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Susan Reed (b) (4)	04 Nov 2020 19:36:55
	(b) (4)	
User opened query 'Per DM CLR: Please confirm if this medication is still ongoing as the noted solicited adverse reaction has already resolved in the Diary card. Reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 18:00:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Susan Reed (b) (4)	25 Sep 2020 17:17:36
	(b) (4)	
User entered 'No (N)'	Susan Reed (b) (4)	28 Aug 2020 17:27:58
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:32
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '26 Aug 2020' reason for change: Data Entry Error	Susan Reed (b) (4)	04 Nov 2020 19:36:55
	(b) (4)	
User entered empty; reason for change Data Entry Error	Susan Reed (b) (4)	25 Sep 2020 17:17:36
	(b) (4)	
User entered '25 Aug 2020'	Susan Reed (b) (4)	28 Aug 2020 17:27:58
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:34
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Per DM CLR: Was this medication taken for solicited event? = NO. However, the Indication reflects one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:07:25
Query 'Per DM CLR: Was this medication taken for solicited event? = NO. However, the Indication reflects one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Otherwise, provide clarification. ' answered with 'data updated' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:20:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:18:21

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event? = NO. However, the Indication reflects one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 01:53:34
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 17:23:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 17:23:12
User entered 'No (N)' reason for change: Data Entry Error	Susan Reed (b) (4)	25 Sep 2020 17:23:12
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 17:17:36
User entered empty; reason for change Data Entry Error	Susan Reed (b) (4)	25 Sep 2020 17:17:36
User entered 'No (N)'	Susan Reed (b) (4)	28 Aug 2020 17:27:58

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
User entered empty.	System	28 Aug 2020 17:27:58

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:18:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
User entered empty.	System	28 Aug 2020 17:27:58

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:49
User entered empty.	System	28 Aug 2020 17:27:58

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:18:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:47
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: ASTRAGALUS PROPINQUUS, PRODUCTSYNONYM: ASTRAGALUS [ASTRAGALUS PROPINQUUS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Aug 2020 12:37:51
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Aug 2020 12:37:51
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 17:29:46
User entered 'Astragalus'	Susan Reed (b) (4)	28 Aug 2020 17:28:55
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:48
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Susan Reed (b) (4)	28 Aug 2020 17:28:55
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:53
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. If confirmed that the indication is correct, please confirm if "Was this medication taken for solicited event?" field should also be updated as HEADACHE is a solicited symptom. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 09:16:48
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. If confirmed that the indication is correct, please confirm if "Was this medication taken for solicited event?" field should also be updated as HEADACHE is a solicited symptom. ' answered with 'Confirmed this is what pt took for her h/a' (Site from DM).	Susan Reed (b) (4) (b) (4)	09 Oct 2020 16:23:44
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. If confirmed that the indication is correct, please confirm if "Was this medication taken for solicited event?" field should also be updated as HEADACHE is a solicited symptom. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 01:53:56
User entered 'headache'	Susan Reed (b) (4) (b) (4)	28 Aug 2020 17:28:55

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:18:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:56
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '30'	Susan Reed (b) (4)	28 Aug 2020 17:28:55
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:50:59
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Other (OTHER)'	Susan Reed (b) (4)	28 Aug 2020 17:28:55
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:16:36
User closed query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 23:16:24
User signature succeeded.	Jesse Clark (b) (4)	16 Apr 2021 22:48:16
	(b) (4)	
Query 'This is not in source document. Please verify and update accordingly.' answered with 'updated per source' (Site from CRA).	Mitchell Stern (b) (4)	16 Apr 2021 21:39:45
	(b) (4)	
Signature has been broken.	Mitchell Stern (b) (4)	16 Apr 2021 21:39:23
	(b) (4)	
User entered 'gtts' reason for change: Per Query Resolution	Mitchell Stern (b) (4)	16 Apr 2021 21:39:23
	(b) (4)	
User opened query 'This is not in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:52:01
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'drops'	Susan Reed (b) (4)	28 Aug 2020 17:28:55
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
	(b) (4), (b) (6)	
User closed query 'This is stated as PRN in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:07:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:07:26
User signature succeeded.	Jesse Clark (b) (4)	16 Apr 2021 22:48:16
	(b) (4)	
Query 'This is stated as PRN in source document. Please verify and update accordingly.' answered with 'updated per source' (Site from CRA).	Mitchell Stern (b) (4)	16 Apr 2021 21:39:59
Signature has been broken.	(b) (4)	
	Mitchell Stern (b) (4)	16 Apr 2021 21:39:23
User entered 'as needed (PRN)' reason for change: Per Query Resolution	(b) (4)	
	Mitchell Stern (b) (4)	16 Apr 2021 21:39:23
User opened query 'This is stated as PRN in source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:52:57
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:04
	(b) (4), (b) (6)	
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'once (ONCE)'	Susan Reed (b) (4)	28 Aug 2020 17:28:55
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:18:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:13
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	28 Aug 2020 17:28:55
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:18:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:52:59
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Susan Reed (b) (4)	28 Aug 2020 17:28:55
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:05
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	28 Aug 2020 17:28:55
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '25 Aug 2020'	Susan Reed (b) (4)	28 Aug 2020 17:28:55
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:18:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:20
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Susan Reed (b) (4)	28 Aug 2020 17:28:55
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:18:08**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Susan Reed (b) (4)	28 Aug 2020 17:28:55
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:28
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '25 Aug 2020'	Susan Reed (b) (4)	28 Aug 2020 17:28:55
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:18:08

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:30
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:47:57
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'This is not an ae, this was captured on ed diary. Pt did ed diary on the 8/26/2020 in the am to reflect data on 8/25/20.' (Site from DM).	Susan Reed (b) (4) (b) (4)	04 Nov 2020 19:39:47

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 18:00:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Susan Reed (b) (4)	09 Oct 2020 16:23:27
User entered 'No (N)'	Susan Reed (b) (4)	28 Aug 2020 17:28:55

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
User entered empty.	System	28 Aug 2020 17:28:55

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
User entered empty.	System	28 Aug 2020 17:28:55



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:51
User entered empty.	System	28 Aug 2020 17:28:55

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:39
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 11:10:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 11:10:33
Data point term sent to Coder	System	04 Nov 2020 20:07:40
Coding entries removed.	Susan Reed (b) (4)	04 Nov 2020 20:07:01
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 21:21:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 21:21:34
Data point term sent to Coder	System	09 Oct 2020 20:55:30
User entered 'Naproxen'	Susan Reed (b) (4)	09 Oct 2020 20:55:27

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:41
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Susan Reed (b) (4)	09 Oct 2020 20:55:27
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:44
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'HEADACHE/Lymphadenopathy, cervical, bilateral' reason for change: Data Entry Error	Susan Reed (b) (4)	04 Nov 2020 20:07:01
	(b) (4)	
User entered 'Headache/swollen glands'	Susan Reed (b) (4)	09 Oct 2020 20:55:27
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:18:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:46
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '440'	Susan Reed (b) (4)	09 Oct 2020 20:55:27
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:48
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'mg (mg)'	Susan Reed (b) (4)	09 Oct 2020 20:55:27
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:50
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 20:55:27
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:52
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'as needed (PRN)'	Susan Reed (b) (4)	09 Oct 2020 20:55:27
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:54
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 20:55:27
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:18:08**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:53:57
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Susan Reed (b) (4)	09 Oct 2020 20:55:27
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:54:00
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	09 Oct 2020 20:55:27
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:54:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '3 Oct 2020'	Susan Reed (b) (4)	09 Oct 2020 20:55:27
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:54:17
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Susan Reed (b) (4)	09 Oct 2020 20:55:27
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:18:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:54:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Susan Reed (b) (4)	09 Oct 2020 20:55:27
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:54:21
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '4 Oct 2020'	Susan Reed (b) (4)	09 Oct 2020 20:55:27
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:54:28
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes, however, the medication was taken not within the solicited period for this subject. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 05:41:35
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes, however, the medication was taken not within the solicited period for this subject. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Susan Reed (b) (4) (b) (4)	04 Nov 2020 20:02:11
User entered 'No (N)' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	04 Nov 2020 20:02:05
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes, however, the medication was taken not within the solicited period for this subject. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 18:01:56
User entered 'Yes (Y)'	Susan Reed (b) (4) (b) (4)	09 Oct 2020 20:55:27



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
User entered empty.	System	09 Oct 2020 20:55:27

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
User entered empty.	System	09 Oct 2020 20:55:27

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:56
User entered empty.	System	09 Oct 2020 20:55:27

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:18:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:54:45
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Dec 2020 13:24:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 13:24:48
Data point term sent to Coder	System	07 Dec 2020 19:05:30
User entered 'Oxycodone'	Mitchell Stern (b) (4) (b) (4)	07 Dec 2020 19:04:57

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:54:48
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 19:04:57
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:54:51
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Pain related to right total knee arthroplasty'	Mitchell Stern (b) (4)	07 Dec 2020 19:04:57
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:18:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:54:52
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '5'	Mitchell Stern (b) (4)	07 Dec 2020 19:04:57
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:54:54
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'mg (mg)'	Mitchell Stern (b) (4)	07 Dec 2020 19:04:57
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:54:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:04:57
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:54:57
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'as needed (PRN)'	Mitchell Stern (b) (4)	07 Dec 2020 19:04:57
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:54:59
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:04:57
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:18:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:01
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	07 Dec 2020 19:04:57
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:18:08**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:05
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:04:57
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '1 Dec 2020'	Mitchell Stern (b) (4)	07 Dec 2020 19:04:57
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:18:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:13
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 19:04:57
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:18:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:15
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Susan Reed (b) (4)	18 Dec 2020 17:00:35
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	07 Dec 2020 19:04:57
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '06 Dec 2020' reason for change: New Information	Susan Reed (b) (4)	18 Dec 2020 17:00:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:04:57
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:20
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 19:04:57
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
User entered empty.	System	07 Dec 2020 19:04:57

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
User entered empty.	System	07 Dec 2020 19:04:57

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:16:57
User entered empty.	System	07 Dec 2020 19:04:57

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:27
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 19:07:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 19:07:45
	(b) (4)	
Data point term sent to Coder	System	07 Dec 2020 19:06:33
User entered 'Tylenol'	Mitchell Stern (b) (4)	07 Dec 2020 19:06:15
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:29
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 23:25:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 23:25:43
User entered 'No (N)' reason for change: Data Entry Error	Susan Reed (b) (4)	07 Dec 2020 23:25:43
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:06:15
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:06:15
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:31
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Pain related to right total knee arthroplasty'	Mitchell Stern (b) (4)	07 Dec 2020 19:06:15
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:18:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:39
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '650'	Mitchell Stern (b) (4)	07 Dec 2020 19:06:15
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:53
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'mg (mg)'	Mitchell Stern (b) (4)	07 Dec 2020 19:06:15
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:56
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:06:15
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:58
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'as needed (PRN)'	Mitchell Stern (b) (4)	07 Dec 2020 19:06:15
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:01
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:06:15
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:18:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	07 Dec 2020 19:06:15
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:05
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:06:15
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '01 Dec 2020'	Mitchell Stern (b) (4)	07 Dec 2020 19:06:15
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:13
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 19:06:15
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:18:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:15
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4)	29 Dec 2020 22:59:47
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	07 Dec 2020 19:06:15
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:23
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '26 Dec 2020' reason for change: New Information	Mitchell Stern (b) (4)	29 Dec 2020 22:59:47
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:06:15
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:26
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 19:06:15
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
User entered empty.	System	07 Dec 2020 19:06:15

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
User entered empty.	System	07 Dec 2020 19:06:15

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:00
User entered empty.	System	07 Dec 2020 19:06:15

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:18:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:37
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;DIPHENHYDRAMINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 19:12:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 19:12:46
Data point term sent to Coder	System	07 Dec 2020 19:07:37
User entered 'Acetaminophen/Diphenhydramine'	Mitchell Stern (b) (4)	07 Dec 2020 19:07:01



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:39
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 19:07:01
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:44
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Pain related to right total knee arthroplasty'	Mitchell Stern (b) (4)	07 Dec 2020 19:07:01
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:18:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:48
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '500/25'	Mitchell Stern (b) (4)	07 Dec 2020 19:07:01
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:53
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'mg (mg)'	Mitchell Stern (b) (4)	07 Dec 2020 19:07:01
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:56
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:07:01
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:58
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'as needed (PRN)'	Mitchell Stern (b) (4)	07 Dec 2020 19:07:01
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:07:01
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:18:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:05
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	07 Dec 2020 19:07:01
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:18:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:07:01
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:12
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '01 Dec 2020'	Mitchell Stern (b) (4)	07 Dec 2020 19:07:01
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:15
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 19:07:01
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:18:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:16
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4)	29 Dec 2020 22:59:25
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	07 Dec 2020 19:07:01
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:23
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '26 Dec 2020' reason for change: New Information	Mitchell Stern (b) (4)	29 Dec 2020 22:59:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:07:01
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:25
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 19:07:01
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
User entered empty.	System	07 Dec 2020 19:07:01

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
User entered empty.	System	07 Dec 2020 19:07:01



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:17:02
User entered empty.	System	07 Dec 2020 19:07:01

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:18:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:32
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 08:05:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 08:05:09
Data point term sent to Coder	System	07 Dec 2020 19:08:40
User entered 'Ducolax'	Mitchell Stern (b) (4)	07 Dec 2020 19:08:05

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:33
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:08:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 19:08:14
User entered 'No (N)' reason for change: Data Entry Error	Mitchell Stern (b) (4)	07 Dec 2020 19:08:14
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:08:05
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:37
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Constipation related to right total knee arthroplasty and associated medications'	Mitchell Stern (b) (4)	07 Dec 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:18:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:39
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '10'	Mitchell Stern (b) (4)	07 Dec 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:41
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'mg (mg)'	Mitchell Stern (b) (4)	07 Dec 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:42
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:45
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'as needed (PRN)'	Mitchell Stern (b) (4)	07 Dec 2020 19:08:05
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:47
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:18:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:48
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	07 Dec 2020 19:08:05
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:18:08**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:49
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:53
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '02 Dec 2020'	Mitchell Stern (b) (4)	07 Dec 2020 19:08:05
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:18:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:57
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 19:08:05
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:18:08**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:00
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '03 Dec 2020'	Mitchell Stern (b) (4)	07 Dec 2020 19:08:05
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 19:08:05
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
User entered empty.	System	07 Dec 2020 19:08:05

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
User entered empty.	System	07 Dec 2020 19:08:05

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:54
User entered empty.	System	07 Dec 2020 19:08:05

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:18:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:15
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 19:14:47
Data point term sent to Coder	System	07 Dec 2020 19:09:41
User entered 'Apixaban'	Mitchell Stern (b) (4)	07 Dec 2020 19:09:04
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	07 Dec 2020 19:09:04
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:24
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Deep Vein Thrombosis Prophylaxis'	Mitchell Stern (b) (4)	07 Dec 2020 19:09:04
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:28
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '2.5'	Mitchell Stern (b) (4)	07 Dec 2020 19:09:04
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:33
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'mg (mg)'	Mitchell Stern (b) (4)	07 Dec 2020 19:09:04
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:35
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:09:04
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:41
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'twice daily (BID)'	Mitchell Stern (b) (4)	07 Dec 2020 19:09:04
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:18:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:48
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:09:04
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:18:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:51
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	07 Dec 2020 19:09:04
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:58:52
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:09:04
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '01 Dec 2020'	Mitchell Stern (b) (4)	07 Dec 2020 19:09:04
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:04
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 19:09:04
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:18:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:07
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mitchell Stern (b) (4)	22 Dec 2020 23:58:59
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	07 Dec 2020 19:09:04
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:08
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '21 Dec 2020' reason for change: New Information	Mitchell Stern (b) (4)	22 Dec 2020 23:58:59
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:09:04
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 19:09:04
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
User entered '2'	System	07 Dec 2020 19:09:04

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
User entered '1'	System	07 Dec 2020 19:09:04

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:24:57
User entered '804 (804)'	System	07 Dec 2020 19:09:04

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:18:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:16
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 10:11:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 10:11:37
Data point term sent to Coder	System	07 Dec 2020 19:10:41
User entered 'Pantoprazole'	Mitchell Stern (b) (4)	07 Dec 2020 19:10:06

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	07 Dec 2020 19:10:06
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:25
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Gastroesophageal Reflux Disease prophylaxis'	Mitchell Stern (b) (4)	07 Dec 2020 19:10:06
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:18:08**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:28
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '40'	Mitchell Stern (b) (4)	07 Dec 2020 19:10:06
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:31
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'mg (mg)'	Mitchell Stern (b) (4)	07 Dec 2020 19:10:06
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:33
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:10:06
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:35
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'as needed (PRN)'	Mitchell Stern (b) (4)	07 Dec 2020 19:10:06
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:18:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:36
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:10:06
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:18:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:40
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	07 Dec 2020 19:10:06
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:43
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:10:06
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:47
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '01 Dec 2020'	Mitchell Stern (b) (4)	07 Dec 2020 19:10:06
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:48
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 19:10:06
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:18:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:51
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mitchell Stern (b) (4)	22 Dec 2020 23:57:30
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	07 Dec 2020 19:10:06
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '21 Dec 2020' reason for change: New Information	Mitchell Stern (b) (4)	22 Dec 2020 23:57:30
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:10:06
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:59:56
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 19:10:06
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
User entered empty.	System	07 Dec 2020 19:10:06

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
User entered empty.	System	07 Dec 2020 19:10:06

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:04
User entered empty.	System	07 Dec 2020 19:10:06

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:18:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:02
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Dec 2020 19:23:47
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Dec 2020 19:23:47
	(b) (4)	
Data point term sent to Coder	System	07 Dec 2020 19:11:42
User entered 'Dexamethasone'	Mitchell Stern (b) (4)	07 Dec 2020 19:11:32
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:11:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 19:11:38
User entered 'No (N)' reason for change: Data Entry Error	Mitchell Stern (b) (4)	07 Dec 2020 19:11:38
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:11:32
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:11:32
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:09
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Pain and inflammation secondary to right total knee arthroplasty'	Mitchell Stern (b) (4)	07 Dec 2020 19:11:32
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:18:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:11
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '2'	Mitchell Stern (b) (4)	07 Dec 2020 19:11:32
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:13
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'mg (mg)'	Mitchell Stern (b) (4)	07 Dec 2020 19:11:32
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:15
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:11:32
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:31
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'once daily (QD)'	Mitchell Stern (b) (4)	07 Dec 2020 19:11:32
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:18:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:33
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:11:32
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:18:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:42
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	07 Dec 2020 19:11:32
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:44
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	07 Dec 2020 19:11:32
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:47
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '03 Dec 2020'	Mitchell Stern (b) (4)	07 Dec 2020 19:11:32
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:18:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:49
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	07 Dec 2020 19:11:32
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:18:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:51
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 19:11:32
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:55
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '05 Dec 2020'	Mitchell Stern (b) (4)	07 Dec 2020 19:11:32
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:00:57
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	07 Dec 2020 19:11:32
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
User entered '1'	System	07 Dec 2020 19:11:32

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
User entered '1'	System	07 Dec 2020 19:11:32



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:06
User entered '804 (804)'	System	07 Dec 2020 19:11:32

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:53:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:53:41
	(b) (4)	
Data point term sent to Coder	System	18 Dec 2020 17:01:41
User entered 'Tramadol'	Susan Reed (b) (4)	18 Dec 2020 17:01:25
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:04
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Susan Reed (b) (4)	18 Dec 2020 17:01:25
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:08
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Post op pain r knee replacement'	Susan Reed (b) (4)	18 Dec 2020 17:01:25
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:18:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '25'	Susan Reed (b) (4)	18 Dec 2020 17:01:25
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:12
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'mg (mg)'	Susan Reed (b) (4)	18 Dec 2020 17:01:25
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:13
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	18 Dec 2020 17:01:25
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:15
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'as needed (PRN)' reason for change:	Susan Reed (b) (4)	18 Dec 2020 17:58:35
Data Entry Error	(b) (4)	
User entered 'every month (QM)'	Susan Reed (b) (4)	18 Dec 2020 17:01:25
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:18:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:17
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	18 Dec 2020 17:01:25
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:18:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:19
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Susan Reed (b) (4)	18 Dec 2020 17:01:25
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:20
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	18 Dec 2020 17:01:25
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:25
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '16 Dec 2020'	Susan Reed (b) (4)	18 Dec 2020 17:01:25
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:18:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:29
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Susan Reed (b) (4)	18 Dec 2020 17:01:25
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:18:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:32
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4)	15 Jan 2021 18:47:47
	(b) (4)	
User entered 'Yes (Y)'	Susan Reed (b) (4)	18 Dec 2020 17:01:25
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:36
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '9 Jan 2021' reason for change: New Information	Mitchell Stern (b) (4)	15 Jan 2021 18:47:53
	(b) (4)	
User entered '1 Jan 2021' reason for change: New Information	Mitchell Stern (b) (4)	15 Jan 2021 18:47:47
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	18 Dec 2020 17:01:25
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:40
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Susan Reed (b) (4)	18 Dec 2020 17:01:25
	(b) (4)	



**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
User entered empty.	System	18 Dec 2020 17:58:35
User entered '1'	System	18 Dec 2020 17:01:25

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
User entered empty.	System	18 Dec 2020 17:58:35
User entered '1'	System	18 Dec 2020 17:01:25

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:10
User entered empty.	System	18 Dec 2020 17:58:35
User entered '802 (802)'	System	18 Dec 2020 17:01:25

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:18:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:45
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 23:33:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	29 Dec 2020 23:03:01
Data point term sent to Coder	System	29 Dec 2020 23:02:00
User entered 'Naproxen'	Mitchell Stern (b) (4)	29 Dec 2020 23:01:30
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:18:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:47
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	29 Dec 2020 23:01:30
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:18:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:51
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Pain related to right total knee arthroplasty' reason for change: Data Entry Error	Mitchell Stern (b) (4)	29 Dec 2020 23:02:05
	(b) (4)	
User entered 'Right knee pain'	Mitchell Stern (b) (4)	29 Dec 2020 23:01:30
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:18:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:54
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 16:02:30
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Dose verified with participant and corrected.' (Site from DM).	Jesse Clark (b) (4)	08 Feb 2021 23:11:04
	(b) (4)	
User entered '250' reason for change: Per Query Resolution	Jesse Clark (b) (4)	08 Feb 2021 23:10:50
	(b) (4)	
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 20:53:25
User entered '200'	Mitchell Stern (b) (4)	29 Dec 2020 23:01:30
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:18:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:02:01
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:01:56
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'mg (mg)'	Mitchell Stern (b) (4)	29 Dec 2020 23:01:30
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:18:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:02:03
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	29 Dec 2020 23:01:30
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:18:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:02:06
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'as needed (PRN)'	Mitchell Stern (b) (4)	29 Dec 2020 23:01:30
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:18:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:02:08
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	29 Dec 2020 23:01:30
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:18:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:02:11
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	29 Dec 2020 23:01:30
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:18:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:02:13
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	29 Dec 2020 23:01:30
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:18:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:02:16
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '27 Dec 2020'	Mitchell Stern (b) (4)	29 Dec 2020 23:01:30
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:18:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:02:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	29 Dec 2020 23:01:30
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:18:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
User signature succeeded.	Jesse Clark (b) (4)	16 Apr 2021 22:48:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:02:20
Signature has been broken.	Mitchell Stern (b) (4)	16 Apr 2021 16:51:59
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4)	16 Apr 2021 16:51:59
	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	29 Dec 2020 23:01:30
	(b) (4)	



US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:18:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
User signature succeeded.	Jesse Clark (b) (4)	16 Apr 2021 22:48:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:02:23
Signature has been broken.	Mitchell Stern (b) (4)	16 Apr 2021 16:51:59
	(b) (4)	
User entered '16 Mar 2021' reason for change: New Information	Mitchell Stern (b) (4)	16 Apr 2021 16:51:59
	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	29 Dec 2020 23:01:30
	(b) (4)	

US3682001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:18:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:02:24
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	29 Dec 2020 23:01:30
	(b) (4)	

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:18:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
User entered empty.	System	29 Dec 2020 23:01:30

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
User entered empty.	System	29 Dec 2020 23:01:30

**US3682001**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:18:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:25:12
User entered empty.	System	29 Dec 2020 23:01:30

US3682001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:18:08

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:13:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:02:33
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
User entered 'Yes (Y)' reason for change: New Information	Susan Reed (b) (4)	02 Dec 2020 22:52:29
User entered 'No (N)'	Jesse Clark (b) (4)	09 Sep 2020 21:18:50

US3682001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:18:08

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:20:01
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered '30 Nov 2020'	Susan Reed (b) (4)	02 Dec 2020 22:53:10
	(b) (4)	

US3682001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:18:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:20:01
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Total right knee replacement'	Susan Reed (b) (4)	02 Dec 2020 22:53:10
	(b) (4)	



**US3682001**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:20:01
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered 'Adverse Event (AE)'	Susan Reed (b) (4)	02 Dec 2020 22:53:10
	(b) (4)	

US3682001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:18:08

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:20:01
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 17:57:35
	(b) (4)	
User entered empty.	Susan Reed (b) (4)	02 Dec 2020 22:53:10
	(b) (4)	

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'USA-US081-2020-MRNA-1273-P301000002'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Yes (Y)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Yes (Y)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01



**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Jesse'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Clark'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '910 Vine Street'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered 'Los Angeles'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'CA'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '90038'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	



**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
User entered 'US'	(b) (4) System	03 Dec 2020 13:21:24

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Jan 2021 14:26:20
User entered '4'	System	30 Dec 2020 14:43:47
User entered '3'	System	16 Dec 2020 19:46:11
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered '2'	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '1'	System	03 Dec 2020 13:21:24

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'USA-US081-2020-MRNA-1273-P301000002'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Yes (Y)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Yes (Y)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01



**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Jesse'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Clark'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '910 Vine Street'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered 'Los Angeles'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'CA'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '90038'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	



**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
User entered 'US'	(b) (4) System	03 Dec 2020 13:21:24

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Jan 2021 14:26:20
User entered '4'	System	30 Dec 2020 14:43:47
User entered '3'	System	16 Dec 2020 19:46:11
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered '2'	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '1'	System	03 Dec 2020 13:21:24

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:18:08**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
User entered '03/Dec/2020 08:21'	(b) (4) System	03 Dec 2020 13:21:24

US3682001

Folder: SAE USA-US081-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:18:08

**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)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:24

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'USA-US081-2020-MRNA-1273-P301000002'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Yes (Y)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01



**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Yes (Y)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Jesse'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Clark'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '910 Vine Street'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered 'Los Angeles'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	



**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'CA'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '90038'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
User entered 'US'	(b) (4) System	03 Dec 2020 13:21:24

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Jan 2021 14:26:20
User entered '4'	System	30 Dec 2020 14:43:47
User entered '3'	System	16 Dec 2020 19:46:11
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered '2'	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '1'	System	03 Dec 2020 13:21:24

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:18:08**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:42:29
User entered '10/Dec/2020 09:51'	System	10 Dec 2020 17:51:11

US3682001

Folder: SAE USA-US081-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:18:08

**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.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
User entered 'I'	(b) (4), (b) (6)	10 Dec 2020 17:51:11

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'USA-US081-2020-MRNA-1273-P301000002'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Yes (Y)'	System	03 Dec 2020 13:21:01



**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Yes (Y)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Jesse'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Clark'	System	03 Dec 2020 13:21:01



**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '910 Vine Street'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered 'Los Angeles'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'CA'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '90038'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
User entered 'US'	(b) (4) System	03 Dec 2020 13:21:24

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Jan 2021 14:26:20
User entered '4'	System	30 Dec 2020 14:43:47
User entered '3'	System	16 Dec 2020 19:46:11
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered '2'	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '1'	System	03 Dec 2020 13:21:24

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:18:08**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:42:29
User entered '16/Dec/2020 13:46'	System	16 Dec 2020 19:46:11

US3682001

Folder: SAE USA-US081-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:18:08

**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.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
User entered 'I'	(b) (4), (b) (6)	16 Dec 2020 19:46:11



**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'USA-US081-2020-MRNA-1273-P301000002'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Yes (Y)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Yes (Y)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01



**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Jesse'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Clark'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '910 Vine Street'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered 'Los Angeles'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'CA'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '90038'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
User entered 'US'	(b) (4) System	03 Dec 2020 13:21:24

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Jan 2021 14:26:20
User entered '4'	System	30 Dec 2020 14:43:47
User entered '3'	System	16 Dec 2020 19:46:11
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered '2'	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '1'	System	03 Dec 2020 13:21:24



**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:18:08**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:42:29
User entered '30/Dec/2020 09:43'	System	30 Dec 2020 14:43:47

US3682001

Folder: SAE USA-US081-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:18:08

**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.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
User entered 'I'	(b) (4), (b) (6)	30 Dec 2020 14:43:47

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'USA-US081-2020-MRNA-1273-P301000002'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Yes (Y)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Yes (Y)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01



**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'No (N)'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Jesse'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'Clark'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '910 Vine Street'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered 'Los Angeles'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 13:21:18
User entered 'CA'	System	03 Dec 2020 13:21:01

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered empty.	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '90038'	Sandy MacNicoll (b) (4)	03 Dec 2020 16:33:20
	(b) (4)	



**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:42:29
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 14:43:51
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
User entered 'US'	(b) (4) System	03 Dec 2020 13:21:24

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:18:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Jan 2021 14:26:20
User entered '4'	System	30 Dec 2020 14:43:47
User entered '3'	System	16 Dec 2020 19:46:11
Signature has been broken.	System	10 Dec 2020 17:51:11
User entered '2'	System	10 Dec 2020 17:51:11
User signature succeeded.	Jesse Clark (b) (4)	03 Dec 2020 22:40:46
	(b) (4)	
User entered '1'	System	03 Dec 2020 13:21:24

**US3682001**

**Folder: SAE USA-US081-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:18:08**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:42:29
User entered '14/Jan/2021 09:26'	System	14 Jan 2021 14:26:20

US3682001

Folder: SAE USA-US081-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:18:08

**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.	Jesse Clark (b) (4)	05 Mar 2021 23:19:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 19:42:29
User entered 'I'	(b) (4), (b) (6)	14 Jan 2021 14:26:20