

US3682163 (Prod: UCLA Vine Street Clinic - (CRS))

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:22:48

All time stamps listed in this document are displayed in GMT

US3682163

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 20:58:24

Generated On: 10 Jun 2021 09:22:48

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[Participant ID](#)

US3682163

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

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US3682163

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3682163

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 23:20:14

Generated On: 10 Jun 2021 09:22:48

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	60
Age Units	YEARS
Age (Derived)	60
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

US3682163

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 23:20:14

Generated On: 10 Jun 2021 09:22:48

Date of Informed Consent ( <i>dd MMM yyyy</i> )	8 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify _____	
Was this participant screened previously?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If Yes, previous participant number	US3682064
Enrollment Trigger	1

US3682163

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3682163

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

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Were any significant conditions reported?

Yes ☒

No ☐

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US3682163

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

Condition	ASTHMA, MILD
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3682163

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

Condition	DIABETES MELLITUS
Start date (dd MMM yyyy)	1 SEP 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3682163

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

Condition	RT KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

US3682163

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

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

US3682163

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

Condition	ALLERGY: SULFA, RASH
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)	_____

US3682163

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

Condition	ALLERGY: IODINE, RASH
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)	

US3682163

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

Condition	ALLERGY: MORPHINE, RASH
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)	

US3682163

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

Condition	OBESITY
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)	

US3682163

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	01 JUN 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3682163

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

Condition	DYSLIPIDEMIA
Start date (dd MMM yyyy)	UN SEP 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3682163

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

Condition	RT KNEE DEGENERATION
Start date (dd MMM yyyy)	
Start date completely unknown	True
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 2008
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

US3682163

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

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

US3682163

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	24 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	12:40 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 12:40
Height ( <i>xxx.x</i> )	66 in
Weight ( <i>xxx.x</i> )	250 lb
BMI ( <i>xxx.x</i> )	40.43543 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)	

US3682163

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3682163

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 23:20:14

Generated On: 10 Jun 2021 09:22:48

Date of assessment (*dd MMM yyyy*) 8 SEP 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (*dd MMM yyyy*) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) 01 JUN 2009

Date of last menstruation unknown False

US3682163

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

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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

US3682163

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 23:20:15

Generated On: 10 Jun 2021 09:22:48

<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>	



US3682163

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3682163

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

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

What was the participant's randomization number? 146736

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 ☒

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Height	ND - Not Done
Weight	ND - Not Done

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

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)	24 SEP 2020
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 12:40
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)	102 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	14:18 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 14:18
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	98 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)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3682163

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3682163

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 13:36 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 13:36

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

US3682163

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 SEP 2020

Collection time (00:00-23:59)

13:29 (24 HR)

Collection date and time (derived)

24 SEP 2020 13:29



US3682163

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:31	24 SEP 2020 13:31
Nasopharyngeal Swab 2	No		

US3682163

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**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

98.2 °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

24 SEP 2020 14:20

PC Open Date & Time

24 SEP 2020 13:56

PC Close Date & Time

24 SEP 2020 16:26

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**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 96.5 °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 SEP 2020 18:04
PC Open Date & Time	24 SEP 2020 17:21
PC Close Date & Time	25 SEP 2020 11:59

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 18:01

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:48

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**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

97.4 °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

26 SEP 2020 18:38

---

PC Open Date & Time

26 SEP 2020 12:00

---

PC Close Date & Time

27 SEP 2020 11:59

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US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**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

95.9 °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

27 SEP 2020 18:00

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**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

95.9 °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 SEP 2020 17:56

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59



US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:22:48

---

**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

95.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 08:22

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**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

95.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 18:02

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**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

24 SEP 2020 14:21

PC Open Date & Time

24 SEP 2020 13:56

PC Close Date & Time

24 SEP 2020 16:26

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 18:04

PC Open Date & Time

24 SEP 2020 17:21

PC Close Date & Time

25 SEP 2020 11:59

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 18:02

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 18:38

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 18:00

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**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 ☐

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

1

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 18:03

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59



US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 08:23

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 18:03

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**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 ☐

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 14:22
PC Open Date & Time	24 SEP 2020 13:56
PC Close Date & Time	24 SEP 2020 16:26

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**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 ☐

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 18:05
PC Open Date & Time	24 SEP 2020 17:21
PC Close Date & Time	25 SEP 2020 11:59

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**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 ☒

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:48

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 18:04
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59



US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:22:48

**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 ☒

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:22:48

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 18:39
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**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 ☒

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:48

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 18:01
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**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)

60 of 2857

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

		Yes <input type="checkbox"/>
PC Time stamp	28 SEP 2020 18:04	
PC Open Date & Time	28 SEP 2020 12:00	
PC Close Date & Time	29 SEP 2020 11:59	

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:22:48

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 ☒

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:22:48

		Yes <input type="checkbox"/>
PC Time stamp	30 SEP 2020 08:23	
PC Open Date & Time	29 SEP 2020 12:00	
PC Close Date & Time	30 SEP 2020 11:59	



US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**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 ☒

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:48

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 18:03
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3682163

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:20:14

Generated On: 10 Jun 2021 09:22:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682163

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:20:14

Generated On: 10 Jun 2021 09:22:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682163

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:20:14

Generated On: 10 Jun 2021 09:22:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682163

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:20:14

Generated On: 10 Jun 2021 09:22:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682163

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:20:14

Generated On: 10 Jun 2021 09:22:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682163

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:20:14

Generated On: 10 Jun 2021 09:22:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3682163

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

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

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 14:35
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	15:40 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 15:40
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)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3682163

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 2020

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

US3682163

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 15:07 (24 HR)

Treatment Date and Time (derived) 22 OCT 2020 15:07

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

US3682163

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 OCT 2020
Collection time (00:00-23:59)	14:55 (24 HR)
Collection date and time (derived)	22 OCT 2020 14:55

US3682163

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Collection date (dd MMM yyyy)			22 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:03	22 OCT 2020 15:03
Nasopharyngeal Swab 2	No		

US3682163

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**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

97.2 °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

22 OCT 2020 15:44

PC Open Date & Time

22 OCT 2020 15:27

PC Close Date & Time

22 OCT 2020 17:57

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 95.0 °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	23 OCT 2020 03:03
PC Open Date & Time	22 OCT 2020 18:52
PC Close Date & Time	23 OCT 2020 11:59

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	96.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	23 OCT 2020 18:30
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:48

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	95.9 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	24 OCT 2020 18:03
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:22:48

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**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

97.2 °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

25 OCT 2020 18:02

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 18:03

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °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

27 OCT 2020 18:08

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:22:48

---

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

96.3 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

28 OCT 2020 13:37

---

PC Open Date & Time

28 OCT 2020 12:00

---

PC Close Date & Time

29 OCT 2020 11:59

---



US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**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

22 OCT 2020 15:44

PC Open Date & Time

22 OCT 2020 15:27

PC Close Date & Time

22 OCT 2020 17:57

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**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

23 OCT 2020 03:03

PC Open Date & Time

22 OCT 2020 18:52

PC Close Date & Time

23 OCT 2020 11:59

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☒

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 OCT 2020 18:32

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:48

**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 OCT 2020 18:04

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 OCT 2020 18:02

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 OCT 2020 18:03

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 OCT 2020 18:09

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 OCT 2020 13:37

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59



US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**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 ☐

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

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

No ☒

Yes ☐

PC Time stamp	22 OCT 2020 15:45
PC Open Date & Time	22 OCT 2020 15:27
PC Close Date & Time	22 OCT 2020 17:57

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**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 ☐

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

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

No ☒

Yes ☐

PC Time stamp	23 OCT 2020 03:04
PC Open Date & Time	22 OCT 2020 18:52
PC Close Date & Time	23 OCT 2020 11:59

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**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 ☒

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:48

		Yes <input type="checkbox"/>
PC Time stamp	23 OCT 2020 18:32	
PC Open Date & Time	23 OCT 2020 12:00	
PC Close Date & Time	24 OCT 2020 11:59	

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:22:48

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 ☒

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:22:48

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 18:04
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59



US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

104 of 2857

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:48

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 18:03
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

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

106 of 2857

EAB) (1725)

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 18:04
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:22:48

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

108 of 2857

EAB) (1725)

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:22:48

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 18:09
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**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 ☒

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:48

		Yes <input type="checkbox"/>
PC Time stamp	28 OCT 2020 13:38	
PC Open Date & Time	28 OCT 2020 12:00	
PC Close Date & Time	29 OCT 2020 11:59	



US3682163

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:20:14

Generated On: 10 Jun 2021 09:22:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682163

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:20:14

Generated On: 10 Jun 2021 09:22:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682163

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682163

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682163

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3682163

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682163

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3682163

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 NOV 2020
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 12:40
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)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3682163

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 NOV 2020

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

US3682163

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 NOV 2020

Collection time (00:00-23:59)

13:02 (24 HR)

Collection date and time (derived)

19 NOV 2020 13:02

US3682163

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:29:07

Generated On: 10 Jun 2021 09:22:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	25 NOV 2020 10:22:21
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 11:57:03
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 19:14:38
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 08:04:53

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 07:23:39
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59



US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 DEC 2020 10:23:40
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 07:25:11

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 18:07:36
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 18:56:45

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 07:06:53
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	False
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	True
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	30 JAN 2021 12:30:00
Patient Cloud Open Date & Time	30 JAN 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
133 of 2857	

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	False
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	True
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 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"/>



**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

08 FEB 2021 16:45:21

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 FEB 2021 15:07:03

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	22 FEB 2021 07:09:25
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 05:25:02

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	10 MAR 2021 13:02:07
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 05:12:19

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 08:21:32

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 00:01:53

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59



US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 11:53:20

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**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

12 APR 2021 07:09:46

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**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

19 APR 2021 15:17:24

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**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

24 APR 2021 00:02:00

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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 <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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59



US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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16 JUN 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

19 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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26 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

03 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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 <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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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21 JUL 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59



US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

07 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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25 AUG 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	18 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 SEP 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**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 ☐

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

25 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

16 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**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 ☐

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59



US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

30 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	13 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2021 23:59
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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59



US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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08 DEC 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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22 DEC 2021 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	25 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

08 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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 <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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**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 ☐

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**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 ☐

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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26 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**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 ☐

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59



US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

19 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**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 ☐

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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26 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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 <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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	02 APR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	06 APR 2022 23:59
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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**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 ☐

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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20 APR 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

30 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

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

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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="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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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="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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59



US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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="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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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20 JUL 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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="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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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27 JUL 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**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 ☐

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59



US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	13 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2022 23:59
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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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24 AUG 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

03 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

10 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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="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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	15 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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="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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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[Patient Cloud Close Date & Time](#)

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26 OCT 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**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 ☐

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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05 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 NOV 2022 23:59

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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

**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 ☐

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	12 NOV 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 NOV 2022 23:59
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US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 NOV 2022 23:59



US3682163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:48

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="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"/>

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

---

Date and time of submission

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	26 NOV 2022 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	30 NOV 2022 23:59
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**US3682163**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 09:22:48**

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		02 MAR 2021 07:39:00

US3682163

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:16:48

Generated On: 10 Jun 2021 09:22:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682163

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:16:48

Generated On: 10 Jun 2021 09:22:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682163

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682163

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682163

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3682163

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682163

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682163

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682163

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 21:59:04

Generated On: 10 Jun 2021 09:22:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 APR 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

US3682163

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 21:59:04

Generated On: 10 Jun 2021 09:22:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 APR 2021
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	22 APR 2021 13:00
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682163

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 21:59:04

Generated On: 10 Jun 2021 09:22:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 APR 2021

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

US3682163

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 21:59:04

Generated On: 10 Jun 2021 09:22:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 APR 2021

Collection time (00:00-23:59)

13:33 (24 HR)

Collection date and time (derived)

22 APR 2021 13:33

US3682163

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 21:59:04

Generated On: 10 Jun 2021 09:22:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3682163**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

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*

**US3682163**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

Date of Contact	25 JAN 2021
Time of Contact	11:30
Date and Time of Contact (derived)	25 JAN 2021 11:30
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

332 of 2857

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

336 of 2857

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

340 of 2857

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

344 of 2857

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

348 of 2857

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

352 of 2857

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 21:13:15

Generated On: 10 Jun 2021 09:22:48

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

Date of Visit	26 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	26 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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US3682163

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	28 JAN 2021
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3682163

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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	SICKD1

US3682163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	26 JAN 2021
Time of assessment ( <i>00:00-23:59</i> )	11:25 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 11:25
Height ( <i>xxx.x</i> )	66 in
Weight ( <i>xxx.x</i> )	ND - Not Done
Temperature ( <i>xxx.x</i> )	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	85 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3682163

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 JAN 2021

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

US3682163

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 JAN 2021

US3682163

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

---

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

---

Visit date (dd MMM yyyy)	13 JAN 2021
--------------------------	-------------

---

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

---

Folder OID	UNBLND_DECIDE
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US3682163

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

Form: Unblinding

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

Date of updated informed consent (dd MMM yyyy) 13 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 13 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3682163

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 JAN 2021

Collection time (00:00-23:59)

11:01 (24 HR)

Collection date and time (derived)

13 JAN 2021 11:01

US3682163

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00 - 23:59)	11:04
Collection Date and Time (derived)	13 JAN 2021 11:04

US3682163

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 21:18:36

Generated On: 10 Jun 2021 09:22:48

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

AEID	USA-US081-2021-MRNA-1273-P30 1000008
Adverse event	RIGHT NEPHRITIS
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)	2 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	2 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	03 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

367 of 2857



US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

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

US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

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PT PRESENTED WITH CHILLS, COUGH, AND GENERALIZED PAIN ON HOSPITAL ADMISSION. ON 2/2/21 (PRIOR TO THE HOSPITAL ADMISSION), THE PT SAID THAT A CXR, COVID PCR TEST, AND AN EKG HAD BEEN PERFORMED. PT IS RECEIVING PAIN MEDICATIONS IN THE HOSPITAL, BUT SHE CANNOT RECALL ANY ANTIBIOTICS ADMINISTERED. THE PT SAID THAT SHE WILL BE GETTING A RIGHT SIDED STENT SOON. A RELEASE OF INFORMATION FORM WAS SENT TO THE PT ON 2/3/21.

FROM HOSPITAL RECORDS: PT RECEIVED A RIGHT URETERAL STENT ON 2/3/21. LAB AND DIAGNOSTIC TEST RESULTS WERE NOT RECEIVED WITHIN REQUESTED MEDICAL RECORDS.

---

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

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US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

AEID	USA-US081-2021-MRNA-1273-P30 1000008
Adverse event	RIGHT URETERAL STONES
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)	2 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	2 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	3 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

370 of 2857

US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	RIGHT KIDNEY STONES DIAGNOSED UPON HOSPITAL ADMISSION ON 2/2/21. PT IS BEING TREATED FOR NEPHRITIS AS AN INPATIENT.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
PRODUCTION RELEASE (v12.003 EAB) (1725)	
371 of 2857	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Data signed:** (b) (4) 01 Apr 2021 20:58:25

**Generated On: 10 Jun 2021 09:22:48**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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0

US3682163

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

AEID

Adverse event

ABDOMINAL PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

4 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

373 of 2857

EAB) (1725)

US3682163

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

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

US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

AEID	
Adverse event	WORSENEDED ASTHMA
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)	29 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

375 of 2857



US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

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 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	PT STARTED TAKING ADVAIR DISKUS AND ALBUTEROL AGAIN. PT WAS PREVIOUSLY PRESCRIBED THESE MEDICATIONS SEVERAL YEARS AGO.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
PRODUCTION RELEASE (v12.003 EAB) (1725)	376 of 2857

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Data signed:** (b) (4) 01 Apr 2021 20:58:25

**Generated On: 10 Jun 2021 09:22:48**

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Admitted to ICU Derived (CSA Programming Field Only)

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US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

AEID	
Adverse event	RIGHT URETERAL STONES
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)	2 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	15 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	17 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

378 of 2857

US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

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	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	

US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

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PT HAD RE-HOSPITALIZATION  
FOR RIGHT URETERAL STONES.  
PT WITH CONTINUED RIGHT  
FLANK PAIN AND ABDOMINAL  
PAIN. PT HAD A RIGHT STENT  
RE-INSERTION ON 3/15/21. PT  
TO HAVE THE STENT REMOVED  
ON 3/22/21. HOSPITALIZATION  
WAS PROLONGED DUE TO THE  
COMPLAINT OF CHEST PAIN  
AND FURTHER CARDIAC  
WORKUP (CHEST PAIN WAS  
NON-CARDIAC).

---

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

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US3682163

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

AEID

Adverse event

NON-CARDIAC CHEST PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

381 of 2857

EAB) (1725)

US3682163

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

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 COMPLAINED OF CHEST PAIN DURING HER 15MAR2021 TO 17MAR2021 HOSPITALIZATION. CARDIAC WORKUP PERFORMED, ACCORDING TO THE PT. ROI FORM SEND TO PT ON 3/18/21 FOR MEDICAL RECORDS FROM THE HOSPITAL

PRODUCTION RELEASE (v12.003  
EAB) (1725)

382 of 2857

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Data signed:** (b) (4) 01 Apr 2021 20:58:25

**Generated On: 10 Jun 2021 09:22:48**

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)	



US3682163

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

AEID

Adverse event

RIGHT FLANK PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

4 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

384 of 2857

EAB) (1725)

US3682163

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

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

US3682163

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

AEID	
Adverse event	COVID-LIKE ILLNESS
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)	23 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

386 of 2857

US3682163

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

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

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

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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.

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US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication DYSLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

389 of 2857

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	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)		17 SEP 2002
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

391 of 2857



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	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 SEP 2001	
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"/>

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication INJ ARM PAIN

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

393 of 2857

EAB) (1725)

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 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)		24 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication BODY ACHES AND HEADACHE

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

395 of 2857

EAB) (1725)

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

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

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

397 of 2857

EAB) (1725)

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	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)	12 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication FLOMAX

Prophylaxis Yes ☐  
No ☒

Indication RIGHT URETERAL STONES

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

399 of 2857



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	4 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 22 MAR 2021		
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"/>

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT NEPHRITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

401 of 2857

EAB) (1725)

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	4 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	11 FEB 2021	
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"/>	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication NORCO

Prophylaxis Yes ☐  
No ☒

Indication RIGHT FLANK AND  
ABDOMINAL PAIN

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

403 of 2857

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

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

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication ADVAIR DISKUS

Prophylaxis Yes ☐  
No ☒

Indication WORSENE ASTHMA

Dose per administration 250/50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

405 of 2857

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	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)	29 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication WORSENE ASTHMA

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

407 of 2857



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

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

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication NOVOLOG

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS

Dose per administration 10

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify AS NEEDED AND BEFORE MEALS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

409 of 2857

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

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

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication FENTANYL

Prophylaxis Yes ☐  
No ☒

Indication RIGHT URETERAL STONES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

411 of 2857

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 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"/>

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication PROPOFOL

Prophylaxis Yes ☐  
No ☒

Indication RIGHT URETERAL STONES

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

413 of 2857

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 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"/>

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication LIDOCAINE 2%

Prophylaxis Yes ☐  
No ☒

Indication RIGHT URETERAL STONES

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

415 of 2857

EAB) (1725)



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	15 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication MIDAZOLAM

Prophylaxis Yes ☐  
No ☒

Indication RIGHT URETERAL STONES

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

417 of 2857

EAB) (1725)

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 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"/>

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication CEFAZOLIN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT URETERAL STONES

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

419 of 2857

EAB) (1725)

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	15 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication ONDANSETRON

Prophylaxis Yes ☐  
No ☒

Indication RIGHT URETERAL STONES

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

421 of 2857

EAB) (1725)

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	15 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication RIGHT URETERAL STONES

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

423 of 2857

EAB) (1725)



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	15 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐  
No ☒

Indication RIGHT URETERAL STONES

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

425 of 2857

EAB) (1725)

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	15 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication METOCLOPRAMIDE

Prophylaxis Yes ☐  
No ☒

Indication RIGHT URETERAL STONES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

427 of 2857

EAB) (1725)

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 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"/>

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT URETERAL STONES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

429 of 2857

EAB) (1725)

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 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"/>

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication PHENYLEPHRINE

Prophylaxis Yes ☐  
No ☒

Indication RIGHT URETERAL STONES

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

431 of 2857

EAB) (1725)



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	15 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication RIGHT URETERAL STONES

Dose per administration 180

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)

433 of 2857

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 08 Apr 2021 18:02:58

Generated On: 10 Jun 2021 09:22:48

	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)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	15 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 01 Apr 2021 20:58:25

Generated On: 10 Jun 2021 09:22:48

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 18:02:59

Generated On: 10 Jun 2021 09:22:48

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
2 FEB 2021	CHEST X-RAY	Adverse Event	
2 FEB 2021	ELECTROCARDIOGRAM	Adverse Event	
2 FEB 2021	CT OF THE ABDOMEN	Adverse Event	
3 FEB 2021	CYTOSCOPY RIGHT URETERAL STENT INSERTION	Adverse Event	
15 MAR 2021	CYTOSCOPY RIGHT URETERAL STENT RE-INSERTION	Adverse Event	
22 MAR 2021	RIGHT URETERAL STENT REMOVAL	Adverse Event	
15 MAR 2021	RIGHT LITHROTRIPSY	Adverse Event	
15 MAR 2021	RIGHT URETERAL STENT REPLACEMENT	Adverse Event	

US3682163

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:22:48

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

US3682163

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:22:48

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 ☐

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

SAEID	USA-US081-2021-MRNA-1273-P301000008
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)	8



US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

SAEID	USA-US081-2021-MRNA-1273-P301000008
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)	8
Date of submission (Pre-filled from custom function)	04/FEB/2021 14:15
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

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

SAEID	USA-US081-2021-MRNA-1273-P301000008
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)	8
Date of submission (Pre-filled from custom function)	16/FEB/2021 11:05
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

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

SAEID	USA-US081-2021-MRNA-1273-P301000008
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)	8
Date of submission (Pre-filled from custom function)	19/FEB/2021 11:36
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

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

SAEID	USA-US081-2021-MRNA-1273-P301000008
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)	8
Date of submission (Pre-filled from custom function)	03/MAR/2021 11:51
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

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

SAEID	USA-US081-2021-MRNA-1273-P301000008
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)	8
Date of submission (Pre-filled from custom function)	04/MAR/2021 11:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

SAEID	USA-US081-2021-MRNA-1273-P301000008
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)	8
Date of submission (Pre-filled from custom function)	10/MAR/2021 14:00
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

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form (7)

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

SAEID	USA-US081-2021-MRNA-1273-P301000008
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)	8
Date of submission (Pre-filled from custom function)	19/MAR/2021 11:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form (8)

Data signed: (b) (4) 01 Apr 2021 20:58:26

Generated On: 10 Jun 2021 09:22:48

SAEID	USA-US081-2021-MRNA-1273-P301000008
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)	8
Date of submission (Pre-filled from custom function)	25/MAR/2021 13:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



Audit

US3682163 (Prod: UCLA Vine Street Clinic - (CRS))

**US3682163**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:22:48**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'US3682163'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 19:59:25

US3682163

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:22:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:11:06

**US3682163**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '24 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 19:59:26

**US3682163**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[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 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Clinic (Clinic)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:11:06

**US3682163**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'SCRN'	System	24 Sep 2020 21:11:06

US3682163

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:48

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered (b) (6) 1960'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 19:59:27

**US3682163**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:48**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '60'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:11:36



**US3682163**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:48**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'YEARS'	System	24 Sep 2020 21:11:36

**US3682163**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:48**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '60'	System	24 Sep 2020 21:12:10

**US3682163**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:48**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Female (F)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:11:36

US3682163

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:48

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 21:11:46
User entered 'Hispanic or Latino (HISPANIC OR LATINO)' reason for change: Data Entry Error	Sandy MacNicoll (b) (4)	24 Sep 2020 21:11:46
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	24 Sep 2020 21:11:36
	Sandy MacNicoll (b) (4)	24 Sep 2020 21:11:36
	(b) (4)	

**US3682163**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:48**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'I'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:11:36

**US3682163**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:48**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:11:36

**US3682163**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:48**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:11:36

**US3682163**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:48**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:11:36



**US3682163**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:48**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:11:36

**US3682163**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:48**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:11:36

**US3682163**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:48**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:11:36

**US3682163**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:48**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:11:36

**US3682163**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:22:48**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:11:36

US3682163

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:48

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '8 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Susan Reed (b) (4)	24 Sep 2020 23:48:46
User entered '9 Sep 2020'	(b) (4)	
	Sandy MacNicoll (b) (4)	24 Sep 2020 21:12:10
	(b) (4)	

**US3682163**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'Sep 2020'	System	24 Sep 2020 21:12:10

**US3682163**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '2020'	System	24 Sep 2020 21:12:10



**US3682163**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:22:48**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Amendment 3 (3)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:12:10

US3682163

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User closed query 'Enrollment is recorded as No; however, met all criteria is recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4)	24 Sep 2020 23:46:58
User entered 'Yes (Y)' reason for change: Per Query Resolution	Susan Reed (b) (4)	24 Sep 2020 23:46:58
User opened query 'Enrollment is recorded as No; however, met all criteria is recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4)	24 Sep 2020 23:46:18
User entered 'No (N)' reason for change: Per Query Resolution	System	24 Sep 2020 23:46:18
User entered 'Yes (Y)'	Susan Reed (b) (4)	24 Sep 2020 23:46:18
	(b) (4)	24 Sep 2020 21:12:10
	Sandy MacNicoll (b) (4)	
	(b) (4)	

US3682163

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:48

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty; reason for change Data Entry Error	(b) (4) Susan Reed (b) (4)	24 Sep 2020 23:46:58
User entered 'Inclusion/Exclusion (INCLUSION/EXCLUSION)' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	24 Sep 2020 23:46:18
User entered empty.	Sandy MacNicoll (b) (4) (b) (4)	24 Sep 2020 21:12:10

**US3682163**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:22:48**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:12:10

**US3682163**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:22:48**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:12:10

**US3682163**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:22:48**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'US3682064'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 19:59:26

**US3682163**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:22:48**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '1'	System	24 Sep 2020 23:46:58
User entered empty.	System	24 Sep 2020 23:46:18
User entered '1'	System	24 Sep 2020 21:12:10

US3682163

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:09:55



**US3682163**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:22:48**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:10:51

US3682163

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 20:18:48
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'not currently on pharmacotherapy' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 21:02:19
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:18:24
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)	24 Sep 2020 22:20:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 22:20:35
Data point term sent to Coder	System	24 Sep 2020 22:20:03
User entered 'ASTHMA, MILD'	(b) (4), (b) (6)	24 Sep 2020 22:19:21

**US3682163**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'UN UNK 1995'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:19:21

**US3682163**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:19:21

**US3682163**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:19:21

**US3682163**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:19:21

**US3682163**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:19:21

**US3682163**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'Jan 1995'	System	24 Sep 2020 22:19:21



**US3682163**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '1995'	System	24 Sep 2020 22:19:21

**US3682163**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	24 Sep 2020 22:19:21

**US3682163**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	24 Sep 2020 22:19:21

US3682163

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 22:20:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 22:20:36
Data point term sent to Coder	System	24 Sep 2020 22:20:03
User entered 'DIABETES MELLITUS'	(b) (4), (b) (6)	24 Sep 2020 22:19:54

**US3682163**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '1 Sep 2001'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:19:54

**US3682163**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:19:54

**US3682163**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:19:54

**US3682163**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:19:54



**US3682163**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:19:54

**US3682163**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'Sep 2001'	System	24 Sep 2020 22:19:54

**US3682163**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '2001'	System	24 Sep 2020 22:19:54

**US3682163**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	24 Sep 2020 22:19:54

**US3682163**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	24 Sep 2020 22:19:54

US3682163

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 20:19:49
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 20:19:47
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'update complete' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 21:04:06
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'update complete' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 21:03:59
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:18:55
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:18:49
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:38:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:38:49
Data point term sent to Coder	System	24 Sep 2020 22:21:04

PRODUCTION RELEASE (v12.003  
EAB) (1725)

501 of 2857

**US3682163**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Condition](#)

Audit	User	Time (GMT)
User entered 'RT KNEE REPLACEMENT'	(b) (4), (b) (6)	24 Sep 2020 22:20:36

**US3682163**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:20:36



**US3682163**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:20:36

**US3682163**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:20:36

**US3682163**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:20:36

**US3682163**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:20:36

**US3682163**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'Jan 2008'	System	24 Sep 2020 22:20:36

**US3682163**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '2008'	System	24 Sep 2020 22:20:36

**US3682163**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'Jan 2008'	System	24 Sep 2020 22:20:36

**US3682163**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '2008'	System	24 Sep 2020 22:20:36



US3682163

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 06:18:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 06:18:42
Data point term sent to Coder	System	24 Sep 2020 22:22:05
User entered 'LFT KNEE REPLACEMENT'	(b) (4), (b) (6)	24 Sep 2020 22:21:07

**US3682163**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'UN UNK 2009'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:21:07

**US3682163**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:21:07

**US3682163**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:21:07

**US3682163**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'UN UNK 2009'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:21:07

**US3682163**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:21:07

**US3682163**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'Jan 2009'	System	24 Sep 2020 22:21:07

**US3682163**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '2009'	System	24 Sep 2020 22:21:07



**US3682163**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'Jan 2009'	System	24 Sep 2020 22:21:07

**US3682163**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '2009'	System	24 Sep 2020 22:21:07

US3682163

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:45:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:45:39
Data point term sent to Coder	System	24 Sep 2020 22:22:05
User entered 'ALLERGY: SULFA, RASH'	(b) (4), (b) (6)	24 Sep 2020 22:21:38

**US3682163**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:21:38

**US3682163**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:21:38

**US3682163**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:21:38

**US3682163**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:21:38

**US3682163**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:21:38



**US3682163**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'Jan 2010'	System	24 Sep 2020 22:21:38

**US3682163**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '2010'	System	24 Sep 2020 22:21:38

**US3682163**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	24 Sep 2020 22:21:38

**US3682163**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	24 Sep 2020 22:21:38

US3682163

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Iodine allergy, LLT: Iodine allergy - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:43:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:43:51
Data point term sent to Coder	System	24 Sep 2020 22:23:08
User entered 'ALLERGY: IODINE, RASH'	(b) (4), (b) (6)	24 Sep 2020 22:22:10

**US3682163**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:22:10

**US3682163**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:22:10

**US3682163**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:22:10



**US3682163**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:22:10

**US3682163**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:22:10

**US3682163**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'Jan 2010'	System	24 Sep 2020 22:22:10

**US3682163**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '2010'	System	24 Sep 2020 22:22:10

**US3682163**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	24 Sep 2020 22:22:10

**US3682163**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	24 Sep 2020 22:22:10

US3682163

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Allergic drug rash - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 14:31:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 14:31:55
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:44:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:44:38
Data point term sent to Coder	System	24 Sep 2020 22:23:06
User entered 'ALLERGY: MORPHINE, RASH'	(b) (4), (b) (6)	24 Sep 2020 22:22:32

**US3682163**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:22:32



**US3682163**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:22:32

**US3682163**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:22:32

**US3682163**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:22:32

**US3682163**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:22:32

**US3682163**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'Jan 2010'	System	24 Sep 2020 22:22:32

**US3682163**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '2010'	System	24 Sep 2020 22:22:32

**US3682163**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	24 Sep 2020 22:22:32

**US3682163**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	24 Sep 2020 22:22:32



US3682163

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Oct 2020 20:33:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:33:25
Data point term sent to Coder	System	06 Oct 2020 20:32:12
User entered 'Obesity'	Susan Reed (b) (4) (b) (4)	06 Oct 2020 20:31:48

**US3682163**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 20:31:48

**US3682163**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'I'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 20:31:48

**US3682163**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 20:31:48

**US3682163**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 20:31:48

**US3682163**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Oct 2020 20:31:48

**US3682163**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	06 Oct 2020 20:31:48

**US3682163**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	06 Oct 2020 20:31:48



**US3682163**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	06 Oct 2020 20:31:48

**US3682163**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	06 Oct 2020 20:31:48

US3682163

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
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)	07 Oct 2020 20:17:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 20:17:29
Data point term sent to Coder	System	07 Oct 2020 20:01:47
User entered 'POST MENOPAUSAL'	(b) (4), (b) (6)	07 Oct 2020 20:00:36

**US3682163**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '01 Jun 2009'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:00:36

**US3682163**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:00:36

**US3682163**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:00:36

**US3682163**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:00:36

**US3682163**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:00:36



**US3682163**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'Jun 2009'	System	07 Oct 2020 20:00:36

**US3682163**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '2009'	System	07 Oct 2020 20:00:36

**US3682163**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	07 Oct 2020 20:00:36

**US3682163**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	07 Oct 2020 20:00:36

US3682163

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Lipid metabolism and deposit disorders NEC, PT: Dyslipidaemia, LLT: Dyslipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 21:04:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 21:04:16
Data point term sent to Coder	System	14 Oct 2020 21:03:06
User entered 'DYSLIPIDEMIA'	(b) (4), (b) (6)	14 Oct 2020 21:03:04

**US3682163**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'UN Sep 2002'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:03:04

**US3682163**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:03:04

**US3682163**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:03:04



**US3682163**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:03:04

**US3682163**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:03:04

**US3682163**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'Sep 2002'	System	14 Oct 2020 21:03:04

**US3682163**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '2002'	System	14 Oct 2020 21:03:04

**US3682163**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	14 Oct 2020 21:03:04

**US3682163**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	14 Oct 2020 21:03:04

US3682163

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
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)	15 Oct 2020 12:06:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 12:06:52
Data point term sent to Coder	System	14 Oct 2020 21:05:08
User entered 'RT KNEE DEGENERATION'	(b) (4), (b) (6)	14 Oct 2020 21:04:50

**US3682163**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:04:50



**US3682163**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:04:50

**US3682163**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:04:50

**US3682163**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:04:50

**US3682163**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:04:50

**US3682163**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	14 Oct 2020 21:04:50

**US3682163**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	14 Oct 2020 21:04:50

**US3682163**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'Jan 2008'	System	14 Oct 2020 21:04:50

**US3682163**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '2008'	System	14 Oct 2020 21:04:50



US3682163

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:22:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Degenerative joint disease - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 21:06:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 21:06:21
Data point term sent to Coder	System	14 Oct 2020 21:06:09
User entered 'LEFT KNEE DEGENERATION'	(b) (4), (b) (6)	14 Oct 2020 21:05:17

**US3682163**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:05:17

**US3682163**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:05:17

**US3682163**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:05:17

**US3682163**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'UN UNK 2009'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:05:17

**US3682163**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:05:17

**US3682163**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	14 Oct 2020 21:05:17

**US3682163**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	14 Oct 2020 21:05:17



**US3682163**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'Jan 2009'	System	14 Oct 2020 21:05:17

**US3682163**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '2009'	System	14 Oct 2020 21:05:17

**US3682163**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:31:31

**US3682163**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '24 Sep 2020'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:31:31

US3682163

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '12:40'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:31:31

**US3682163**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '24 Sep 2020 12:40'	System	24 Sep 2020 21:31:31

US3682163

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
DataPoint set to visible.	(b) (4)	24 Sep 2020 23:46:58
DataPoint set to invisible.	System	24 Sep 2020 23:46:18
User entered '66' in	Sandy MacNicoll (b) (4)	24 Sep 2020 21:31:31
DataPoint set to visible.	(b) (4)	24 Sep 2020 21:12:10

US3682163

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
DataPoint set to visible.	(b) (4)	24 Sep 2020 23:46:58
DataPoint set to invisible.	System	24 Sep 2020 23:46:18
User entered '250' lb	Sandy MacNicoll (b) (4)	24 Sep 2020 21:31:31
DataPoint set to visible.	(b) (4)	24 Sep 2020 21:12:10



US3682163

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User closed query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 13:51:49
Query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' answered with 'medical history updated' (Site from DM).	Susan Reed (b) (4) (b) (4)	06 Oct 2020 20:31:13
User opened query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 23:32:09
DataPoint set to visible.	System	24 Sep 2020 23:46:58
DataPoint set to invisible.	System	24 Sep 2020 23:46:18
User entered '40.43543'	System	24 Sep 2020 21:31:31
DataPoint set to visible.	System	24 Sep 2020 21:12:10

**US3682163**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
DataPoint set to visible.	System	24 Sep 2020 23:46:58
DataPoint set to invisible.	System	24 Sep 2020 23:46:18
User entered 'kg/m2'	System	24 Sep 2020 21:31:31
DataPoint set to visible.	System	24 Sep 2020 21:12:10

US3682163

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered missing code ND - Not Done.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:31:31

US3682163

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:31:31

**US3682163**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:31:31

**US3682163**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered missing code ND - Not Done.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:31:31

**US3682163**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'bpm'	System	24 Sep 2020 21:31:31

US3682163

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered missing code ND - Not Done.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:31:31



**US3682163**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'breaths/min'	System	24 Sep 2020 21:31:31

US3682163

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered missing code ND - Not Done.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:31:31

**US3682163**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'mmHg'	System	24 Sep 2020 21:31:31

US3682163

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered missing code ND - Not Done.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:31:31

**US3682163**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'mmHg'	System	24 Sep 2020 21:31:31

**US3682163**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38

**US3682163**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38

**US3682163**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:10:42



**US3682163**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:48**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 22:10:42

US3682163

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:22:48

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
	(b) (4)	
User entered '8 Sep 2020' reason for change: Data Entry Error	Susan Reed (b) (4)	24 Sep 2020 23:48:28
	(b) (4)	
User closed query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	System	24 Sep 2020 23:47:24
User entered '9 Sep 2020' reason for change: Data Entry Error	Susan Reed (b) (4)	24 Sep 2020 23:47:24
	(b) (4)	
User opened query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	System	24 Sep 2020 21:35:11
User entered '24 Sep 2020'	Sandy MacNicoll (b) (4)	24 Sep 2020 21:35:11
	(b) (4)	

US3682163

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:22:48

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:35:11

US3682163

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:22:48

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
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)	08 Oct 2020 19:12:36
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 'data recorded. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 20:02:01
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)	07 Oct 2020 06:47:02
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Sandy MacNicoll (b) (4) (b) (4)	24 Sep 2020 21:35:11

**US3682163**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:22:48**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:35:11

US3682163

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:22:48

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:35:11

**US3682163**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:22:48**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:35:11

**US3682163**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '01 Jun 2009'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:35:11



**US3682163**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:22:48**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:35:11

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

[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 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

**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 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

**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 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

**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 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

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 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

[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 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

**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 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22



US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

**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 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

[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 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

**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 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

**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 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22



US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

**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 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

[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 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

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 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'I'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '0'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

US3682163

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:36:22

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:09:42

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '24 Sep 2020'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:09:42



**US3682163**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[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 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Clinic (Clinic)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:09:42

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'VISIT1'	System	24 Sep 2020 21:09:42

US3682163

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '24 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 20:04:35

US3682163

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:48

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '146736'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 20:04:35

US3682163

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:48

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 20:04:35

US3682163

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:48

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 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:10:55

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:22:48**

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 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'No (N)'	Sandy MacNicoll (b) (4)	24 Sep 2020 21:10:55

US3682163

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:48

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User closed query 'Per CDM: per sponsor review, BMI ≥ 40 kg/m2 yet participant is not recorded as at risk. Please reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 09:26:48
Query 'Per CDM: per sponsor review, BMI ≥ 40 kg/m2 yet participant is not recorded as at risk. Please reconcile' answered with 'form updated' (Site from DM).	Susan Reed (b) (4) (b) (4)	23 Nov 2020 21:25:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Susan Reed (b) (4) (b) (4)	23 Nov 2020 21:24:26
User opened query 'Per CDM: per sponsor review, BMI ≥ 40 kg/m2 yet participant is not recorded as at risk. Please reconcile' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 19:41:55
User entered 'No (N)'	Sandy MacNicoll (b) (4) (b) (4)	24 Sep 2020 21:10:55



**US3682163**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:22:48**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:10:55

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:22:48**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:10:55

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:22:48**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:33
DataPoint set to visible.	(b) (4) System	24 Sep 2020 21:12:10

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered missing code ND - Not Done.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered missing code ND - Not Done.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered missing code ND - Not Done.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered missing code ND - Not Done.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User accepted default value 'Pre-Dose (PREDOSE)'	Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13



US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '24 Sep 2020'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:48**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '12:40'	(b) (4) Sandy MacNicoll (b) (4) (b) (4)	24 Sep 2020 21:39:13

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered '24 Sep 2020 12:40'	System	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '97.2' F	Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Oral (Oral)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered empty.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '102'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13



US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'bpm'	System	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '18'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'breaths/min'	System	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '120'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'mmHg'	System	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '80'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'mmHg'	System	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered missing code ND - Not Done.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13



US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered missing code ND - Not Done.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User accepted default value 'Post-Dose (POSTDOSE)'	Sandy MacNicoll (b) (4) (b) (4)	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '24 Sep 2020'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '14:18'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered '24 Sep 2020 14:18'	System	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '98.2' F	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Oral (Oral)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13



**US3682163**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered empty.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '98'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'bpm'	System	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '16'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'breaths/min'	System	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '131'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'mmHg'	System	24 Sep 2020 21:39:13

US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '83'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:13



US3682163

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'mmHg'	System	24 Sep 2020 21:39:13

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'No (N)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:40:01

US3682163

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered empty.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:40:01

US3682163

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:12:41

US3682163

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:48

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered empty.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:12:41

US3682163

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:48

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 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered empty.	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:12:41

US3682163

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 21:12:41

US3682163

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '24 Sep 2020'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:12:41



US3682163

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '13:36'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:12:41

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:48**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered '24 Sep 2020 13:36'	System	24 Sep 2020 21:12:41

US3682163

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Left Arm (LEFT ARM)'	Sandy MacNicoll (b) (4)	24 Sep 2020 21:12:41

US3682163

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'ONCE'	System	24 Sep 2020 21:12:41

US3682163

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 21:12:41

US3682163

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 23:55:05

US3682163

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 23:55:05

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '13:29'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 23:55:05



**US3682163**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered '24 Sep 2020 13:29'	System	24 Sep 2020 23:55:05

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:22:48**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 23:55:19

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	24 Sep 2020 23:55:19

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 23:55:19

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '13:31'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 23:55:19

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered '24 Sep 2020 13:31'	System	24 Sep 2020 23:55:19

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	24 Sep 2020 23:55:19

US3682163

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 23:55:19



**US3682163**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 23:55:19

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered empty.	System	24 Sep 2020 23:55:19

US3682163

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:22:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) Sandy MacNicoll (b) (4)	24 Sep 2020 21:39:24

**US3682163**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'I'	System	24 Sep 2020 21:39:24

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T14:19:57', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '20d61b82-f256-4de8-9363-7bd5638a4235'	System	24 Sep 2020 21:20:31
User entered 'Yes (Y)'	System	24 Sep 2020 21:20:31

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T14:20:08', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '20d61b82-f256-4de8-9363-7bd5638a4235'	System	24 Sep 2020 21:20:31
User entered '98.2'	System	24 Sep 2020 21:20:31

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T14:20:14', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '20d61b82-f256-4de8-9363-7bd5638a4235'	System	24 Sep 2020 21:20:31
User entered 'No (N)'	System	24 Sep 2020 21:20:31



**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T14:20:26', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '20d61b82-f256-4de8-9363-7bd5638a4235'	System	24 Sep 2020 21:20:31
User entered '24 Sep 2020 14:20'	System	24 Sep 2020 21:20:31

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '24 Sep 2020 13:56'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '24 Sep 2020 16:26'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T18:03:56', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c32518db-fe8e-4340-ae5e-bd83d4be0529'	System	25 Sep 2020 01:04:26
User entered 'Yes (Y)'	System	25 Sep 2020 01:04:26

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T18:04:07', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c32518db-fe8e-4340-ae5e-bd83d4be0529'	System	25 Sep 2020 01:04:26
User entered '96.5'	System	25 Sep 2020 01:04:26

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T18:04:16', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c32518db-fe8e-4340-ae5e-bd83d4be0529'	System	25 Sep 2020 01:04:26
User entered 'No (N)'	System	25 Sep 2020 01:04:26

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T18:04:22', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c32518db-fe8e-4340-ae5e-bd83d4be0529'	System	25 Sep 2020 01:04:26
User entered '24 Sep 2020 18:04'	System	25 Sep 2020 01:04:26



US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '24 Sep 2020 17:21'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 2'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-25T18:01:07', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'faec5ddb-2e36-48ef-bca4-69c4ea98da03'	System	26 Sep 2020 01:09:54
User entered 'Yes (Y)'	System	26 Sep 2020 01:09:54

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-25T18:01:13', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'faec5ddb-2e36-48ef-bca4-69c4ea98da03'	System	26 Sep 2020 01:09:54
User entered '98.6'	System	26 Sep 2020 01:09:54

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-25T18:01:26', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'faec5ddb-2e36-48ef-bca4-69c4ea98da03'	System	26 Sep 2020 01:09:54
User entered 'No (N)'	System	26 Sep 2020 01:09:54

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-25T18:01:31', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'faec5ddb-2e36-48ef-bca4-69c4ea98da03'	System	26 Sep 2020 01:09:54
User entered '25 Sep 2020 18:01'	System	26 Sep 2020 01:09:54

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 21:12:41



**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 3'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-26T18:37:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'd8ebe60d-b3d2-47d9-8096-69bcd73a9309'	System	27 Sep 2020 01:38:17
User entered 'Yes (Y)'	System	27 Sep 2020 01:38:17

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-26T18:38:01', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'd8ebe60d-b3d2-47d9-8096-69bcd73a9309'	System	27 Sep 2020 01:38:17
User entered '97.4'	System	27 Sep 2020 01:38:17

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-26T18:38:06', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'd8ebe60d-b3d2-47d9-8096-69bcd73a9309'	System	27 Sep 2020 01:38:17
User entered 'No (N)'	System	27 Sep 2020 01:38:17

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-26T18:38:11', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'd8ebe60d-b3d2-47d9-8096-69bcd73a9309'	System	27 Sep 2020 01:38:17
User entered '26 Sep 2020 18:38'	System	27 Sep 2020 01:38:17

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 21:12:41



US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 4'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:22:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-27T18:00:15', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ce0acbe7-dc40-48ea-91d4-84162ff381f7'	System	28 Sep 2020 01:00:39
User entered 'Yes (Y)'	System	28 Sep 2020 01:00:39

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:22:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-27T18:00:20', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ce0acbe7-dc40-48ea-91d4-84162ff381f7'	System	28 Sep 2020 01:00:39
User entered '95.9'	System	28 Sep 2020 01:00:39

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-27T18:00:24', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ce0acbe7-dc40-48ea-91d4-84162ff381f7'	System	28 Sep 2020 01:00:39
User entered 'No (N)'	System	28 Sep 2020 01:00:39

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-27T18:00:32', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ce0acbe7-dc40-48ea-91d4-84162ff381f7'	System	28 Sep 2020 01:00:39
User entered '27 Sep 2020 18:00'	System	28 Sep 2020 01:00:39

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:22:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:22:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 5'	System	24 Sep 2020 21:12:41



US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T17:56:36', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '3eadf2fa-ec3f-4075-867d-89a644b02015'	System	29 Sep 2020 00:57:04
User entered 'Yes (Y)'	System	29 Sep 2020 00:57:04

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T17:56:49', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '3eadf2fa-ec3f-4075-867d-89a644b02015'	System	29 Sep 2020 00:57:04
User entered '95.9'	System	29 Sep 2020 00:57:04

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T17:56:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '3eadf2fa-ec3f-4075-867d-89a644b02015'	System	29 Sep 2020 00:57:04
User entered 'No (N)'	System	29 Sep 2020 00:57:04

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T17:56:58', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '3eadf2fa-ec3f-4075-867d-89a644b02015'	System	29 Sep 2020 00:57:04
User entered '28 Sep 2020 17:56'	System	29 Sep 2020 00:57:04

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 6'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:22:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T08:22:19', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '981897a3-1e38-4038-8e9d-bbceac69bff4'	System	30 Sep 2020 15:22:52
User entered 'Yes (Y)'	System	30 Sep 2020 15:22:52



US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:22:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T08:22:25', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '981897a3-1e38-4038-8e9d-bbceac69bff4'	System	30 Sep 2020 15:22:52
User entered '95.7'	System	30 Sep 2020 15:22:52

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T08:22:42', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '981897a3-1e38-4038-8e9d-bbceac69bff4'	System	30 Sep 2020 15:22:52
User entered 'No (N)'	System	30 Sep 2020 15:22:52

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T08:22:47', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '981897a3-1e38-4038-8e9d-bbceac69bff4'	System	30 Sep 2020 15:22:52
User entered '30 Sep 2020 08:22'	System	30 Sep 2020 15:22:52

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:22:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 7'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:22:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T18:02:44', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '2f37c4f5-886c-43e4-8cda-f9e806c20e99'	System	01 Oct 2020 01:03:00
User entered 'Yes (Y)'	System	01 Oct 2020 01:03:00

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:22:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T18:02:49', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '2f37c4f5-886c-43e4-8cda-f9e806c20e99'	System	01 Oct 2020 01:03:00
User entered '95.1'	System	01 Oct 2020 01:03:00



US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T18:02:52', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '2f37c4f5-886c-43e4-8cda-f9e806c20e99'	System	01 Oct 2020 01:03:00
User entered 'No (N)'	System	01 Oct 2020 01:03:00

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T18:02:55', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '2f37c4f5-886c-43e4-8cda-f9e806c20e99'	System	01 Oct 2020 01:03:00
User entered '30 Sep 2020 18:02'	System	01 Oct 2020 01:03:00

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:22:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T14:20:49', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '7415dc1b-92e8-412b-a429-3a51fdc81e1f'	System	24 Sep 2020 21:21:23
User entered 'None (1)'	System	24 Sep 2020 21:21:23

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T14:20:56', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '7415dc1b-92e8-412b-a429-3a51fdc81e1f'	System	24 Sep 2020 21:21:23
User entered 'No (N)'	System	24 Sep 2020 21:21:23

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T14:21:03', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '7415dc1b-92e8-412b-a429-3a51fdc81e1f'	System	24 Sep 2020 21:21:23
User entered 'No (N)'	System	24 Sep 2020 21:21:23



US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T14:21:08', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '7415dc1b-92e8-412b-a429-3a51fdc81e1f'	System	24 Sep 2020 21:21:23
User entered 'None (1)'	System	24 Sep 2020 21:21:23

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T14:21:17', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '7415dc1b-92e8-412b-a429-3a51fdc81e1f'	System	24 Sep 2020 21:21:23
User entered '24 Sep 2020 14:21'	System	24 Sep 2020 21:21:23

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '24 Sep 2020 13:56'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '24 Sep 2020 16:26'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T18:04:37', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '9281ac64-c33f-432c-8e7a-3aa7203de46b'	System	25 Sep 2020 01:04:57
User entered 'None (1)'	System	25 Sep 2020 01:04:57

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T18:04:40', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '9281ac64-c33f-432c-8e7a-3aa7203de46b'	System	25 Sep 2020 01:04:57
User entered 'No (N)'	System	25 Sep 2020 01:04:57

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T18:04:43', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '9281ac64-c33f-432c-8e7a-3aa7203de46b'	System	25 Sep 2020 01:04:57
User entered 'No (N)'	System	25 Sep 2020 01:04:57



US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T18:04:48', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '9281ac64-c33f-432c-8e7a-3aa7203de46b'	System	25 Sep 2020 01:04:57
User entered 'None (1)'	System	25 Sep 2020 01:04:57

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T18:04:51', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '9281ac64-c33f-432c-8e7a-3aa7203de46b'	System	25 Sep 2020 01:04:57
User entered '24 Sep 2020 18:04'	System	25 Sep 2020 01:04:57

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '24 Sep 2020 17:21'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 2'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-25T18:02:06', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ad49a793-e696-42fa-b34b-2daf8ad0b15e'	System	26 Sep 2020 01:10:54
User entered 'None (1)'	System	26 Sep 2020 01:10:54

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-25T18:02:11', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ad49a793-e696-42fa-b34b-2daf8ad0b15e'	System	26 Sep 2020 01:10:54
User entered 'No (N)'	System	26 Sep 2020 01:10:54

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-25T18:02:24', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ad49a793-e696-42fa-b34b-2daf8ad0b15e'	System	26 Sep 2020 01:10:54
User entered 'No (N)'	System	26 Sep 2020 01:10:54



US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-25T18:02:33', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ad49a793-e696-42fa-b34b-2daf8ad0b15e'	System	26 Sep 2020 01:10:54
User entered 'None (1)'	System	26 Sep 2020 01:10:54

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-25T18:02:37', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ad49a793-e696-42fa-b34b-2daf8ad0b15e'	System	26 Sep 2020 01:10:54
User entered '25 Sep 2020 18:02'	System	26 Sep 2020 01:10:54

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 3'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-26T18:38:34', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '4366b2b7-f4fb-4701-acc1-9b3acb1c60b1'	System	27 Sep 2020 01:38:59
User entered 'None (1)'	System	27 Sep 2020 01:38:59

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-26T18:38:37', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '4366b2b7-f4fb-4701-acc1-9b3acb1c60b1'	System	27 Sep 2020 01:38:59
User entered 'No (N)'	System	27 Sep 2020 01:38:59

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-26T18:38:41', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '4366b2b7-f4fb-4701-acc1-9b3acb1c60b1'	System	27 Sep 2020 01:38:59
User entered 'No (N)'	System	27 Sep 2020 01:38:59



US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-26T18:38:50', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '4366b2b7-f4fb-4701-acc1-9b3acb1c60b1'	System	27 Sep 2020 01:38:59
User entered 'None (1)'	System	27 Sep 2020 01:38:59

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-26T18:38:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '4366b2b7-f4fb-4701-acc1-9b3acb1c60b1'	System	27 Sep 2020 01:38:59
User entered '26 Sep 2020 18:38'	System	27 Sep 2020 01:38:59

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 4'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-27T18:00:43', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '8dc260d0-2270-4ef8-87b8-b1c8aaca7460'	System	28 Sep 2020 01:01:07
User entered 'None (1)'	System	28 Sep 2020 01:01:07

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-27T18:00:47', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '8dc260d0-2270-4ef8-87b8-b1c8aaea7460'	System	28 Sep 2020 01:01:07
User entered 'No (N)'	System	28 Sep 2020 01:01:07

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-27T18:00:51', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '8dc260d0-2270-4ef8-87b8-b1c8aaea7460'	System	28 Sep 2020 01:01:07
User entered 'No (N)'	System	28 Sep 2020 01:01:07



US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-27T18:00:56', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '8dc260d0-2270-4ef8-87b8-b1c8aaca7460'	System	28 Sep 2020 01:01:07
User entered 'None (1)'	System	28 Sep 2020 01:01:07

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-27T18:00:59', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '8dc260d0-2270-4ef8-87b8-b1c8aaea7460'	System	28 Sep 2020 01:01:07
User entered '27 Sep 2020 18:00'	System	28 Sep 2020 01:01:07

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 5'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T17:57:06', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'abfcf92e-9a4e-431e-845b-8e43088562eb'	System	29 Sep 2020 01:03:44
User entered 'None (1)'	System	29 Sep 2020 01:03:44

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T17:57:08', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'abfcf92e-9a4e-431e-845b-8e43088562eb'	System	29 Sep 2020 01:03:44
User entered 'Yes (Y)'	System	29 Sep 2020 01:03:44

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:48

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T18:03:11', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'abfcf92e-9a4e-431e-845b-8e43088562eb' User entered '1'	System	29 Sep 2020 01:03:44
	System	29 Sep 2020 01:03:44



US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T18:03:22', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'abfcf92e-9a4e-431e-845b-8e43088562eb'	System	29 Sep 2020 01:03:44
User entered 'No (N)'	System	29 Sep 2020 01:03:44

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T18:03:24', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'abfcf92e-9a4e-431e-845b-8e43088562eb'	System	29 Sep 2020 01:03:44
User entered 'None (1)'	System	29 Sep 2020 01:03:44

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T18:03:28', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'abfcf92e-9a4e-431e-845b-8e43088562eb'	System	29 Sep 2020 01:03:44
User entered '28 Sep 2020 18:03'	System	29 Sep 2020 01:03:44

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 6'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T08:22:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ce767223-bfe8-42cc-9a44-bce659cdd7a0'	System	30 Sep 2020 15:23:19
User entered 'None (1)'	System	30 Sep 2020 15:23:19

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T08:22:58', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ce767223-bfe8-42cc-9a44-bce659cdd7a0'	System	30 Sep 2020 15:23:19
User entered 'No (N)'	System	30 Sep 2020 15:23:19



US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T08:23:03', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ce767223-bfe8-42cc-9a44-bce659cdd7a0'	System	30 Sep 2020 15:23:19
User entered 'No (N)'	System	30 Sep 2020 15:23:19

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T08:23:11', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ce767223-bfe8-42cc-9a44-bce659cdd7a0'	System	30 Sep 2020 15:23:19
User entered 'None (1)'	System	30 Sep 2020 15:23:19

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T08:23:16', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ce767223-bfe8-42cc-9a44-bce659cdd7a0'	System	30 Sep 2020 15:23:19
User entered '30 Sep 2020 08:23'	System	30 Sep 2020 15:23:19

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 7'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T18:02:58', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'd67f454e-4f12-40ea-91d1-1a3a69246173'	System	01 Oct 2020 01:03:14
User entered 'None (1)'	System	01 Oct 2020 01:03:14

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T18:03:01', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'd67f454e-4f12-40ea-91d1-1a3a69246173'	System	01 Oct 2020 01:03:14
User entered 'No (N)'	System	01 Oct 2020 01:03:14



US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T18:03:05', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'd67f454e-4f12-40ea-91d1-1a3a69246173'	System	01 Oct 2020 01:03:14
User entered 'No (N)'	System	01 Oct 2020 01:03:14

US3682163

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T18:03:10', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'd67f454e-4f12-40ea-91d1-1a3a69246173'	System	01 Oct 2020 01:03:14
User entered 'None (1)'	System	01 Oct 2020 01:03:14

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T18:03:12', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'd67f454e-4f12-40ea-91d1-1a3a69246173'	System	01 Oct 2020 01:03:14
User entered '30 Sep 2020 18:03'	System	01 Oct 2020 01:03:14

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T14:21:24', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '26cda3e6-3a46-46aa-b23a-773f3a0e7859'	System	24 Sep 2020 21:22:16
User entered 'None (0)'	System	24 Sep 2020 21:22:16

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T14:21:27', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '26cda3e6-3a46-46aa-b23a-773f3a0e7859'	System	24 Sep 2020 21:22:16
User entered 'None (0)'	System	24 Sep 2020 21:22:16



US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T14:21:31', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '26cda3e6-3a46-46aa-b23a-773f3a0e7859'	System	24 Sep 2020 21:22:16
User entered 'None (0)'	System	24 Sep 2020 21:22:16

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T14:21:37', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '26cda3e6-3a46-46aa-b23a-773f3a0e7859'	System	24 Sep 2020 21:22:16
User entered 'None (0)'	System	24 Sep 2020 21:22:16

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T14:21:40', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '26cda3e6-3a46-46aa-b23a-773f3a0e7859'	System	24 Sep 2020 21:22:16
User entered 'None (0)'	System	24 Sep 2020 21:22:16

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T14:21:56', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '26cda3e6-3a46-46aa-b23a-773f3a0e7859'	System	24 Sep 2020 21:22:16
User entered 'None (0)'	System	24 Sep 2020 21:22:16

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T14:22:02', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '26cda3e6-3a46-46aa-b23a-773f3a0e7859'	System	24 Sep 2020 21:22:16
User entered 'No (N)'	System	24 Sep 2020 21:22:16

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T14:22:09', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '26cda3e6-3a46-46aa-b23a-773f3a0e7859'	System	24 Sep 2020 21:22:16
User entered '24 Sep 2020 14:22'	System	24 Sep 2020 21:22:16

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '24 Sep 2020 13:56'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '24 Sep 2020 16:26'	System	24 Sep 2020 21:12:41



US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T18:04:55', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '586d5b1f-1871-4e06-92ac-debfc1e1fe87'	System	25 Sep 2020 01:05:27
User entered 'None (0)'	System	25 Sep 2020 01:05:27

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T18:04:58', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '586d5b1f-1871-4e06-92ac-debfc1e1fe87'	System	25 Sep 2020 01:05:27
User entered 'None (0)'	System	25 Sep 2020 01:05:27

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T18:05:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '586d5b1f-1871-4e06-92ac-debfc1e1fe87'	System	25 Sep 2020 01:05:27
User entered 'None (0)'	System	25 Sep 2020 01:05:27

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T18:05:03', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '586d5b1f-1871-4e06-92ac-debfc1e1fe87'	System	25 Sep 2020 01:05:27
User entered 'None (0)'	System	25 Sep 2020 01:05:27

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T18:05:08', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '586d5b1f-1871-4e06-92ac-debfc1e1fe87'	System	25 Sep 2020 01:05:27
User entered 'None (0)'	System	25 Sep 2020 01:05:27

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T18:05:11', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '586d5b1f-1871-4e06-92ac-debfc1e1fe87'	System	25 Sep 2020 01:05:27
User entered 'None (0)'	System	25 Sep 2020 01:05:27

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T18:05:19', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '586d5b1f-1871-4e06-92ac-debfc1e1fe87'	System	25 Sep 2020 01:05:27
User entered 'No (N)'	System	25 Sep 2020 01:05:27



**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-24T18:05:22', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '586d5b1f-1871-4e06-92ac-debfc1e1fe87'	System	25 Sep 2020 01:05:27
User entered '24 Sep 2020 18:05'	System	25 Sep 2020 01:05:27

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '24 Sep 2020 17:21'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 2'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-25T18:02:47', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'eb9e25cf-9455-4a38-9a50-470a3631e79e'	System	26 Sep 2020 01:14:38
User entered 'None (0)'	System	26 Sep 2020 01:14:38

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-25T18:03:32', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'eb9e25cf-9455-4a38-9a50-470a3631e79e'	System	26 Sep 2020 01:14:38
User entered 'Some interference with activity (2)'	System	26 Sep 2020 01:14:38

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-25T18:03:49', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'eb9e25cf-9455-4a38-9a50-470a3631e79e'	System	26 Sep 2020 01:14:38
User entered 'None (0)'	System	26 Sep 2020 01:14:38

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-25T18:03:57', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'eb9e25cf-9455-4a38-9a50-470a3631e79e'	System	26 Sep 2020 01:14:38
User entered 'None (0)'	System	26 Sep 2020 01:14:38



US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-25T18:04:31', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'eb9e25cf-9455-4a38-9a50-470a3631e79e'	System	26 Sep 2020 01:14:38
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	26 Sep 2020 01:14:38

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-25T18:04:36', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'eb9e25cf-9455-4a38-9a50-470a3631e79e'	System	26 Sep 2020 01:14:38
User entered 'None (0)'	System	26 Sep 2020 01:14:38

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-25T18:04:45', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'eb9e25cf-9455-4a38-9a50-470a3631e79e'	System	26 Sep 2020 01:14:38
User entered 'No (N)'	System	26 Sep 2020 01:14:38

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-25T18:04:51', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'eb9e25cf-9455-4a38-9a50-470a3631e79e'	System	26 Sep 2020 01:14:38
User entered '25 Sep 2020 18:04'	System	26 Sep 2020 01:14:38

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 3'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:22:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-26T18:38:59', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '22927651-6381-408c-a37a-78c93951b18f' User entered 'None (0)'	System	27 Sep 2020 01:39:39
	System	27 Sep 2020 01:39:39



US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:22:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-26T18:39:08', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '22927651-6381-408c-a37a-78c93951b18f' User entered 'None (0)'	System	27 Sep 2020 01:39:39
	System	27 Sep 2020 01:39:39

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:22:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-26T18:39:14', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '22927651-6381-408c-a37a-78c93951b18f' User entered 'None (0)'	System	27 Sep 2020 01:39:39
	System	27 Sep 2020 01:39:39

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:22:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-26T18:39:18', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '22927651-6381-408c-a37a-78c93951b18f' User entered 'None (0)'	System	27 Sep 2020 01:39:39
	System	27 Sep 2020 01:39:39

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-26T18:39:23', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '22927651-6381-408c-a37a-78c93951b18f' User entered 'None (0)'	System	27 Sep 2020 01:39:39
	System	27 Sep 2020 01:39:39

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-26T18:39:27', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '22927651-6381-408c-a37a-78c93951b18f' User entered 'None (0)'	System	27 Sep 2020 01:39:39
	System	27 Sep 2020 01:39:39

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-26T18:39:31', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '22927651-6381-408c-a37a-78c93951b18f' User entered 'No (N)'	System	27 Sep 2020 01:39:39
	System	27 Sep 2020 01:39:39

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-26T18:39:34', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '22927651-6381-408c-a37a-78c93951b18f' User entered '26 Sep 2020 18:39'	System	27 Sep 2020 01:39:39
	System	27 Sep 2020 01:39:39

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 21:12:41



**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 4'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-27T18:01:04', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '72c6a0fd-f056-4e90-871b-b1203875e232'	System	28 Sep 2020 01:01:33
User entered 'None (0)'	System	28 Sep 2020 01:01:33

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-27T18:01:07', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '72c6a0fd-f056-4e90-871b-b1203875e232'	System	28 Sep 2020 01:01:33
User entered 'None (0)'	System	28 Sep 2020 01:01:33

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-27T18:01:10', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '72c6a0fd-f056-4e90-871b-b1203875e232'	System	28 Sep 2020 01:01:33
User entered 'None (0)'	System	28 Sep 2020 01:01:33

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-27T18:01:11', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '72c6a0fd-f056-4e90-871b-b1203875e232'	System	28 Sep 2020 01:01:33
User entered 'None (0)'	System	28 Sep 2020 01:01:33

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-27T18:01:14', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '72c6a0fd-f056-4e90-871b-b1203875e232'	System	28 Sep 2020 01:01:33
User entered 'None (0)'	System	28 Sep 2020 01:01:33

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-27T18:01:16', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '72c6a0fd-f056-4e90-871b-b1203875e232'	System	28 Sep 2020 01:01:33
User entered 'None (0)'	System	28 Sep 2020 01:01:33



US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-27T18:01:22', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '72c6a0fd-f056-4e90-871b-b1203875e232'	System	28 Sep 2020 01:01:33
User entered 'No (N)'	System	28 Sep 2020 01:01:33

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-27T18:01:25', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '72c6a0fd-f056-4e90-871b-b1203875e232'	System	28 Sep 2020 01:01:33
User entered '27 Sep 2020 18:01'	System	28 Sep 2020 01:01:33

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 5'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T18:03:34', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ba38054b-a543-496a-9ed3-24e5c4a10fd1'	System	29 Sep 2020 01:04:06
User entered 'None (0)'	System	29 Sep 2020 01:04:06

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T18:03:37', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ba38054b-a543-496a-9ed3-24e5c4a10fd1'	System	29 Sep 2020 01:04:06
User entered 'None (0)'	System	29 Sep 2020 01:04:06

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T18:03:38', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ba38054b-a543-496a-9ed3-24e5c4a10fd1'	System	29 Sep 2020 01:04:06
User entered 'None (0)'	System	29 Sep 2020 01:04:06



US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T18:03:40', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ba38054b-a543-496a-9ed3-24e5c4a10fd1'	System	29 Sep 2020 01:04:06
User entered 'None (0)'	System	29 Sep 2020 01:04:06

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T18:03:46', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ba38054b-a543-496a-9ed3-24e5c4a10fd1'	System	29 Sep 2020 01:04:06
User entered 'None (0)'	System	29 Sep 2020 01:04:06

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T18:03:48', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ba38054b-a543-496a-9ed3-24e5c4a10fd1'	System	29 Sep 2020 01:04:06
User entered 'None (0)'	System	29 Sep 2020 01:04:06

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T18:03:59', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ba38054b-a543-496a-9ed3-24e5c4a10fd1'	System	29 Sep 2020 01:04:06
User entered 'No (N)'	System	29 Sep 2020 01:04:06

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-28T18:04:03', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ba38054b-a543-496a-9ed3-24e5c4a10fd1'	System	29 Sep 2020 01:04:06
User entered '28 Sep 2020 18:04'	System	29 Sep 2020 01:04:06

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 6'	System	24 Sep 2020 21:12:41



US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:22:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T08:23:22', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '0885a3d7-2cc8-4b4d-ae3c-5ff7915d3481'	System	30 Sep 2020 15:23:50
User entered 'None (0)'	System	30 Sep 2020 15:23:50

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T08:23:24', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '0885a3d7-2cc8-4b4d-ae3c-5ff7915d3481'	System	30 Sep 2020 15:23:50
User entered 'None (0)'	System	30 Sep 2020 15:23:50

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:22:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T08:23:27', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '0885a3d7-2cc8-4b4d-ae3c-5ff7915d3481'	System	30 Sep 2020 15:23:50
User entered 'None (0)'	System	30 Sep 2020 15:23:50

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:22:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T08:23:29', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '0885a3d7-2cc8-4b4d-ae3c-5ff7915d3481'	System	30 Sep 2020 15:23:50
User entered 'None (0)'	System	30 Sep 2020 15:23:50

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:22:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T08:23:31', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '0885a3d7-2cc8-4b4d-ae3c-5ff7915d3481'	System	30 Sep 2020 15:23:50
User entered 'None (0)'	System	30 Sep 2020 15:23:50

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T08:23:33', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '0885a3d7-2cc8-4b4d-ae3c-5ff7915d3481'	System	30 Sep 2020 15:23:50
User entered 'None (0)'	System	30 Sep 2020 15:23:50

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T08:23:42', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '0885a3d7-2cc8-4b4d-ae3c-5ff7915d3481'	System	30 Sep 2020 15:23:50
User entered 'No (N)'	System	30 Sep 2020 15:23:50

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T08:23:45', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '0885a3d7-2cc8-4b4d-ae3c-5ff7915d3481'	System	30 Sep 2020 15:23:50
User entered '30 Sep 2020 08:23'	System	30 Sep 2020 15:23:50



**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	24 Sep 2020 21:12:41
User entered 'Day 7'	System	24 Sep 2020 21:12:41

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T18:03:16', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c4381dda-6c85-4dda-915a-dcbe54b1851f'	System	01 Oct 2020 01:03:36
User entered 'None (0)'	System	01 Oct 2020 01:03:36

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T18:03:18', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c4381dda-6c85-4dda-915a-dcbe54b1851f'	System	01 Oct 2020 01:03:36
User entered 'None (0)'	System	01 Oct 2020 01:03:36

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T18:03:20', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c4381dda-6c85-4dda-915a-dcbe54b1851f'	System	01 Oct 2020 01:03:36
User entered 'None (0)'	System	01 Oct 2020 01:03:36

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T18:03:22', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c4381dda-6c85-4dda-915a-dcbe54b1851f'	System	01 Oct 2020 01:03:36
User entered 'None (0)'	System	01 Oct 2020 01:03:36

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T18:03:24', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c4381dda-6c85-4dda-915a-dcbe54b1851f'	System	01 Oct 2020 01:03:36
User entered 'None (0)'	System	01 Oct 2020 01:03:36



US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T18:03:26', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c4381dda-6c85-4dda-915a-dcbe54b1851f'	System	01 Oct 2020 01:03:36
User entered 'None (0)'	System	01 Oct 2020 01:03:36

US3682163

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T18:03:29', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c4381dda-6c85-4dda-915a-dcbe54b1851f'	System	01 Oct 2020 01:03:36
User entered 'No (N)'	System	01 Oct 2020 01:03:36

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-09-30T18:03:32', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c4381dda-6c85-4dda-915a-dcbe54b1851f'	System	01 Oct 2020 01:03:36
User entered '30 Sep 2020 18:03'	System	01 Oct 2020 01:03:36

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 21:12:41

**US3682163**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:02:43

**US3682163**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '1 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:02:43

**US3682163**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:02:43



**US3682163**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	Susan Reed (b) (4)	01 Oct 2020 20:02:43

US3682163

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	01 Oct 2020 20:02:56

**US3682163**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'I'	System	01 Oct 2020 20:02:56

**US3682163**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:30:48
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	Susan Reed (b) (4)	08 Oct 2020 20:35:11

**US3682163**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:30:48
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '8 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	08 Oct 2020 20:35:11

**US3682163**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:30:48
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	08 Oct 2020 20:35:11

**US3682163**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:30:48
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	08 Oct 2020 20:35:11

**US3682163**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:30:48
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	08 Oct 2020 20:35:16



**US3682163**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:30:48
User entered 'I'	System	08 Oct 2020 20:35:16

**US3682163**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:30:48
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	15 Oct 2020 19:27:04

**US3682163**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:30:48
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered '15 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	15 Oct 2020 19:27:04

**US3682163**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:30:48
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	15 Oct 2020 19:27:04

**US3682163**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:30:48
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	15 Oct 2020 19:27:04

US3682163

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:30:48
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	15 Oct 2020 19:27:09

**US3682163**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:30:48
User entered 'I'	System	15 Oct 2020 19:27:09

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 22:59:19



**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '22 Oct 2020'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 22:59:19

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[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 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Clinic (Clinic)'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 22:59:19

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'VISIT2'	System	22 Oct 2020 22:59:19

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User accepted default value 'Pre-Dose (PREDOSE)'	Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '22 Oct 2020'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:48**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '14:35'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered '22 Oct 2020 14:35'	System	22 Oct 2020 23:00:34



US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '96.9' F	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Oral (Oral)'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered empty.	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '98'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'bpm'	System	22 Oct 2020 23:00:34

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '16'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'breaths/min'	System	22 Oct 2020 23:00:34

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '135'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34



**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'mmHg'	System	22 Oct 2020 23:00:34

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '94'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'mmHg'	System	22 Oct 2020 23:00:34

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User accepted default value 'Post-Dose (POSTDOSE)'	Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '22 Oct 2020'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '15:40'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered '22 Oct 2020 15:40'	System	22 Oct 2020 23:00:34



US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '97.2' F	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Oral (Oral)'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered empty.	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '90'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'bpm'	System	22 Oct 2020 23:00:34

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '15'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'breaths/min'	System	22 Oct 2020 23:00:34

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '132'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34



US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'mmHg'	System	22 Oct 2020 23:00:34

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '89'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:34

US3682163

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'mmHg'	System	22 Oct 2020 23:00:34

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:00:57

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:48**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '22 Oct 2020'	Simone Riley (b) (4)	22 Oct 2020 23:00:57

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:48**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 22:33:56

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:48**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered empty.	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 22:33:56

US3682163

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:48

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 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered empty.	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 22:33:56



US3682163

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'MRNA-1273 OR PLACEBO'	System	22 Oct 2020 22:33:56

US3682163

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '22 Oct 2020'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 22:33:56

US3682163

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '15:07'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 22:33:56

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:22:48**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered '22 Oct 2020 15:07'	System	22 Oct 2020 22:33:56

US3682163

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Left Arm (LEFT ARM)'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 22:33:56

US3682163

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'ONCE'	System	22 Oct 2020 22:33:56

US3682163

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'INTRAMUSCULAR'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 01:01:47



**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:48**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 01:01:47

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '14:55'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 01:01:47

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered '22 Oct 2020 14:55'	System	23 Oct 2020 01:01:47

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:22:48**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 01:02:10

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	23 Oct 2020 01:02:10

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 01:02:10

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '15:03'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 01:02:10

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered '22 Oct 2020 15:03'	System	23 Oct 2020 01:02:10



**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	23 Oct 2020 01:02:10

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 01:02:10

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 01:02:10

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered empty.	System	23 Oct 2020 01:02:10

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	22 Oct 2020 23:01:02

**US3682163**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'I'	System	22 Oct 2020 23:01:02

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-22T15:43:56', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'b670fca0-d9e3-4c9e-85a8-74b1b4759a98'	System	22 Oct 2020 22:44:16
User entered 'Yes (Y)'	System	22 Oct 2020 22:44:16



US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-22T15:44:01', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'b670fca0-d9e3-4c9e-85a8-74b1b4759a98'	System	22 Oct 2020 22:44:16
User entered '97.2'	System	22 Oct 2020 22:44:16

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-22T15:44:06', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'b670fca0-d9e3-4c9e-85a8-74b1b4759a98'	System	22 Oct 2020 22:44:16
User entered 'No (N)'	System	22 Oct 2020 22:44:16

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-22T15:44:12', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'b670fca0-d9e3-4c9e-85a8-74b1b4759a98'	System	22 Oct 2020 22:44:16
User entered '22 Oct 2020 15:44'	System	22 Oct 2020 22:44:16

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '22 Oct 2020 15:27'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '22 Oct 2020 17:57'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T03:02:37', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '6d7eac6d-4411-4d7d-b397-b50207ff9ed5'	System	23 Oct 2020 10:03:30
User entered 'Yes (Y)'	System	23 Oct 2020 10:03:30

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T03:02:58', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '6d7eac6d-4411-4d7d-b397-b50207ff9ed5'	System	23 Oct 2020 10:03:30
User entered '95.0'	System	23 Oct 2020 10:03:30



US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T03:03:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '6d7eac6d-4411-4d7d-b397-b50207ff9ed5'	System	23 Oct 2020 10:03:30
User entered 'No (N)'	System	23 Oct 2020 10:03:30

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T03:03:28', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '6d7eac6d-4411-4d7d-b397-b50207ff9ed5'	System	23 Oct 2020 10:03:30
User entered '23 Oct 2020 03:03'	System	23 Oct 2020 10:03:30

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '22 Oct 2020 18:52'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 2'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:29:47', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '7ca80dc4-584d-4c36-94da-6b281ece76ff'	System	24 Oct 2020 01:30:18
User entered 'Yes (Y)'	System	24 Oct 2020 01:30:18

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:29:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '7ca80dc4-584d-4c36-94da-6b281ece76ff' User entered '96.3'	System	24 Oct 2020 01:30:18
	System	24 Oct 2020 01:30:18

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:29:58', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '7ca80dc4-584d-4c36-94da-6b281ece76ff'	System	24 Oct 2020 01:30:18
User entered 'Yes (Y)'	System	24 Oct 2020 01:30:18



US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
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 'see conmed sheet' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 12:19:50
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)	26 Oct 2020 18:41:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:30:07', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '7ca80dc4-584d-4c36-94da-6b281ece76ff'	(b) (4)	
User entered '1'	System	24 Oct 2020 01:30:18
	System	24 Oct 2020 01:30:18
	System	24 Oct 2020 01:30:18

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:30:07', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '7ca80dc4-584d-4c36-94da-6b281ece76ff' User entered '0'	System	24 Oct 2020 01:30:18
	System	24 Oct 2020 01:30:18

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:30:16', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '7ca80dc4-584d-4c36-94da-6b281ece76ff'	System	24 Oct 2020 01:30:18
User entered '23 Oct 2020 18:30'	System	24 Oct 2020 01:30:18

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:22:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 3'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:03:13', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'cdc06c8f-17e0-47ae-aef2-939f7367818c'	System	25 Oct 2020 01:04:02
User entered 'Yes (Y)'	System	25 Oct 2020 01:04:02

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:03:23', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'cdc06c8f-17e0-47ae-aef2-939f7367818c'	System	25 Oct 2020 01:04:02
User entered '95.9'	System	25 Oct 2020 01:04:02



US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:03:30', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'cdc06c8f-17e0-47ae-aef2-939f7367818c'	System	25 Oct 2020 01:04:02
User entered 'Yes (Y)'	System	25 Oct 2020 01:04:02

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
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 'see conmed sheet' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 13:32:03
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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:03:39', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'cdc06c8f-17e0-47ae-aef2-939f7367818c'	Susan Reed (b) (4)	26 Oct 2020 18:41:56
User entered '1'	System	25 Oct 2020 01:04:02

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:03:39', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'cdc06c8f-17e0-47ae-aef2-939f7367818c' User entered '0'	System	25 Oct 2020 01:04:02
	System	25 Oct 2020 01:04:02

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:03:57', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'cdc06c8f-17e0-47ae-aef2-939f7367818c'	System	25 Oct 2020 01:04:02
User entered '24 Oct 2020 18:03'	System	25 Oct 2020 01:04:02

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:22:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 4'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:22:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-25T18:02:13', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '1366bb28-7551-499b-bc15-36bcde933f46'	System	26 Oct 2020 01:02:28
User entered 'Yes (Y)'	System	26 Oct 2020 01:02:28



US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:22:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-25T18:02:19', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '1366bb28-7551-499b-bc15-36bcde933f46'	System	26 Oct 2020 01:02:28
User entered '97.2'	System	26 Oct 2020 01:02:28

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-25T18:02:22', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '1366bb28-7551-499b-bc15-36bcde933f46'	System	26 Oct 2020 01:02:28
User entered 'No (N)'	System	26 Oct 2020 01:02:28

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-25T18:02:26', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '1366bb28-7551-499b-bc15-36bcde933f46'	System	26 Oct 2020 01:02:28
User entered '25 Oct 2020 18:02'	System	26 Oct 2020 01:02:28

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:22:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 5'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-26T18:03:23', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '27584e9b-b44a-4b47-8fa5-74fc0b6012d5'	System	27 Oct 2020 01:03:44
User entered 'Yes (Y)'	System	27 Oct 2020 01:03:44

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-26T18:03:32', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '27584e9b-b44a-4b47-8fa5-74fc0b6012d5'	System	27 Oct 2020 01:03:44
User entered '97.1'	System	27 Oct 2020 01:03:44



US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-26T18:03:37', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '27584e9b-b44a-4b47-8fa5-74fc0b6012d5'	System	27 Oct 2020 01:03:44
User entered 'No (N)'	System	27 Oct 2020 01:03:44

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-26T18:03:41', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '27584e9b-b44a-4b47-8fa5-74fc0b6012d5'	System	27 Oct 2020 01:03:44
User entered '26 Oct 2020 18:03'	System	27 Oct 2020 01:03:44

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:22:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 6'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:22:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-27T18:07:53', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '516b2a22-ed46-483a-a89a-bd494866e18d'	System	28 Oct 2020 01:08:59
User entered 'Yes (Y)'	System	28 Oct 2020 01:08:59

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:22:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-27T18:08:05', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '516b2a22-ed46-483a-a89a-bd494866e18d' User entered '96.4'	System	28 Oct 2020 01:08:59
	System	28 Oct 2020 01:08:59

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-27T18:08:50', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '516b2a22-ed46-483a-a89a-bd494866e18d'	System	28 Oct 2020 01:08:59
User entered 'No (N)'	System	28 Oct 2020 01:08:59



**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-27T18:08:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '516b2a22-ed46-483a-a89a-bd494866e18d' User entered '27 Oct 2020 18:08'	System	28 Oct 2020 01:08:59
	System	28 Oct 2020 01:08:59

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 7'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:22:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-28T13:37:05', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '232175d6-a921-4489-8d7c-3ca195a013f6'	System	28 Oct 2020 20:37:27
User entered 'Yes (Y)'	System	28 Oct 2020 20:37:27

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:22:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-28T13:37:16', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '232175d6-a921-4489-8d7c-3ca195a013f6' User entered '96.3'	System	28 Oct 2020 20:37:27
	System	28 Oct 2020 20:37:27

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-28T13:37:18', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '232175d6-a921-4489-8d7c-3ca195a013f6'	System	28 Oct 2020 20:37:27
User entered 'No (N)'	System	28 Oct 2020 20:37:27

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-28T13:37:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '232175d6-a921-4489-8d7c-3ca195a013f6' User entered '28 Oct 2020 13:37'	System	28 Oct 2020 20:37:27
	System	28 Oct 2020 20:37:27



US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:22:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:22:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-22T15:44:20', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c4c07ac9-23ae-4570-93f8-b4faf51aa3af'	System	22 Oct 2020 22:44:53
User entered 'None (1)'	System	22 Oct 2020 22:44:53

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-22T15:44:28', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c4c07ac9-23ae-4570-93f8-b4faf51aa3af'	System	22 Oct 2020 22:44:53
User entered 'No (N)'	System	22 Oct 2020 22:44:53

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-22T15:44:38', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c4c07ac9-23ae-4570-93f8-b4faf51aa3af'	System	22 Oct 2020 22:44:53
User entered 'No (N)'	System	22 Oct 2020 22:44:53

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-22T15:44:44', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c4c07ac9-23ae-4570-93f8-b4faf51aa3af'	System	22 Oct 2020 22:44:53
User entered 'None (1)'	System	22 Oct 2020 22:44:53

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-22T15:44:47', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c4c07ac9-23ae-4570-93f8-b4faf51aa3af'	System	22 Oct 2020 22:44:53
User entered '22 Oct 2020 15:44'	System	22 Oct 2020 22:44:53



**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '22 Oct 2020 15:27'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '22 Oct 2020 17:57'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T03:03:37', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'a16b06cb-a12c-47c4-989a-af92f50023fc'	System	23 Oct 2020 10:03:57
User entered 'None (1)'	System	23 Oct 2020 10:03:57

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T03:03:41', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'a16b06cb-a12c-47c4-989a-af92f50023fc'	System	23 Oct 2020 10:03:57
User entered 'No (N)'	System	23 Oct 2020 10:03:57

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T03:03:47', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'a16b06cb-a12c-47c4-989a-af92f50023fc'	System	23 Oct 2020 10:03:57
User entered 'No (N)'	System	23 Oct 2020 10:03:57

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T03:03:50', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'a16b06cb-a12c-47c4-989a-af92f50023fc'	System	23 Oct 2020 10:03:57
User entered 'None (1)'	System	23 Oct 2020 10:03:57

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T03:03:53', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'a16b06cb-a12c-47c4-989a-af92f50023fc'	System	23 Oct 2020 10:03:57
User entered '23 Oct 2020 03:03'	System	23 Oct 2020 10:03:57



**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '22 Oct 2020 18:52'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 2'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:30:53', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '84151803-cd2a-4d1c-808b-0198c827a22a'	System	24 Oct 2020 01:32:26
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		24 Oct 2020 01:32:26

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:30:57', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '84151803-cd2a-4d1c-808b-0198c827a22a'	System	24 Oct 2020 01:32:26
User entered 'No (N)'	System	24 Oct 2020 01:32:26

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:31:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '84151803-cd2a-4d1c-808b-0198c827a22a'	System	24 Oct 2020 01:32:26
User entered 'No (N)'	System	24 Oct 2020 01:32:26

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:32:20', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '84151803-cd2a-4d1c-808b-0198c827a22a'	System	24 Oct 2020 01:32:26
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	24 Oct 2020 01:32:26

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:32:23', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '84151803-cd2a-4d1c-808b-0198c827a22a'	System	24 Oct 2020 01:32:26
User entered '23 Oct 2020 18:32'	System	24 Oct 2020 01:32:26



**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 3'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:04:12', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '02074893-00cc-4bef-a66a-a3cf0c2610fd'	System	25 Oct 2020 01:04:32
User entered 'None (1)'	System	25 Oct 2020 01:04:32

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:04:15', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '02074893-00cc-4bef-a66a-a3cf0c2610fd'	System	25 Oct 2020 01:04:32
User entered 'No (N)'	System	25 Oct 2020 01:04:32

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:04:19', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '02074893-00cc-4bef-a66a-a3cf0c2610fd'	System	25 Oct 2020 01:04:32
User entered 'No (N)'	System	25 Oct 2020 01:04:32

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:04:23', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '02074893-00cc-4bef-a66a-a3cf0c2610fd'	System	25 Oct 2020 01:04:32
User entered 'None (1)'	System	25 Oct 2020 01:04:32

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:04:26', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '02074893-00cc-4bef-a66a-a3cf0c2610fd'	System	25 Oct 2020 01:04:32
User entered '24 Oct 2020 18:04'	System	25 Oct 2020 01:04:32



US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:22:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 4'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-25T18:02:41', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5bfaacae-eac6-437b-9146-2c988e09b573'	System	26 Oct 2020 01:02:54
User entered 'None (1)'	System	26 Oct 2020 01:02:54

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-25T18:02:39', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5bfaacae-eac6-437b-9146-2c988e09b573'	System	26 Oct 2020 01:02:54
User entered 'No (N)'	System	26 Oct 2020 01:02:54

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-25T18:02:44', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5bfaacae-eac6-437b-9146-2c988e09b573'	System	26 Oct 2020 01:02:54
User entered 'No (N)'	System	26 Oct 2020 01:02:54

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-25T18:02:48', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5bfaacae-eac6-437b-9146-2c988e09b573'	System	26 Oct 2020 01:02:54
User entered 'None (1)'	System	26 Oct 2020 01:02:54

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-25T18:02:52', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5bfaacae-eac6-437b-9146-2c988e09b573'	System	26 Oct 2020 01:02:54
User entered '25 Oct 2020 18:02'	System	26 Oct 2020 01:02:54



US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:22:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 5'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-26T18:03:45', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '46338bae-97fa-4bae-bfc2-a3a4f34fa4b8'	System	27 Oct 2020 01:04:00
User entered 'None (1)'	System	27 Oct 2020 01:04:00

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-26T18:03:48', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '46338bae-97fa-4bae-bfc2-a3a4f34fa4b8'	System	27 Oct 2020 01:04:00
User entered 'No (N)'	System	27 Oct 2020 01:04:00

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-26T18:03:51', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '46338bae-97fa-4bae-bfc2-a3a4f34fa4b8'	System	27 Oct 2020 01:04:00
User entered 'No (N)'	System	27 Oct 2020 01:04:00

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-26T18:03:53', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '46338bae-97fa-4bae-bfc2-a3a4f34fa4b8'	System	27 Oct 2020 01:04:00
User entered 'None (1)'	System	27 Oct 2020 01:04:00

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-26T18:03:56', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '46338bae-97fa-4bae-bfc2-a3a4f34fa4b8'	System	27 Oct 2020 01:04:00
User entered '26 Oct 2020 18:03'	System	27 Oct 2020 01:04:00



US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:22:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 6'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-27T18:09:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '423b54fc-2b2f-4989-8cc5-5c4d45ede51f'	System	28 Oct 2020 01:09:14
User entered 'None (1)'	System	28 Oct 2020 01:09:14

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-27T18:09:03', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '423b54fc-2b2f-4989-8cc5-5c4d45ede51f'	System	28 Oct 2020 01:09:14
User entered 'No (N)'	System	28 Oct 2020 01:09:14

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-27T18:09:05', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '423b54fc-2b2f-4989-8cc5-5c4d45ede51f'	System	28 Oct 2020 01:09:14
User entered 'No (N)'	System	28 Oct 2020 01:09:14

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-27T18:09:07', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '423b54fc-2b2f-4989-8cc5-5c4d45ede51f'	System	28 Oct 2020 01:09:14
User entered 'None (1)'	System	28 Oct 2020 01:09:14

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-27T18:09:10', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '423b54fc-2b2f-4989-8cc5-5c4d45ede51f'	System	28 Oct 2020 01:09:14
User entered '27 Oct 2020 18:09'	System	28 Oct 2020 01:09:14



**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 7'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-28T13:37:25', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '1d2b5332-99e7-4d38-9755-c1e28784937d'	System	28 Oct 2020 20:38:07
User entered 'None (1)'	System	28 Oct 2020 20:38:07

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-28T13:37:43', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '1d2b5332-99e7-4d38-9755-c1e28784937d'	System	28 Oct 2020 20:38:07
User entered 'No (N)'	System	28 Oct 2020 20:38:07

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-28T13:37:46', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '1d2b5332-99e7-4d38-9755-c1e28784937d'	System	28 Oct 2020 20:38:07
User entered 'No (N)'	System	28 Oct 2020 20:38:07

US3682163

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-28T13:37:48', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '1d2b5332-99e7-4d38-9755-c1e28784937d'	System	28 Oct 2020 20:38:07
User entered 'None (1)'	System	28 Oct 2020 20:38:07

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-28T13:37:58', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '1d2b5332-99e7-4d38-9755-c1e28784937d' User entered '28 Oct 2020 13:37'	System	28 Oct 2020 20:38:07
	System	28 Oct 2020 20:38:07



**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-22T15:45:04', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '90e5eb72-4c5d-44fe-98e7-4052dc113d53'	System	22 Oct 2020 22:45:33
User entered 'None (0)'	System	22 Oct 2020 22:45:33

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-22T15:45:07', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '90e5eb72-4c5d-44fe-98e7-4052dc113d53'	System	22 Oct 2020 22:45:33
User entered 'None (0)'	System	22 Oct 2020 22:45:33

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-22T15:45:10', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '90e5eb72-4c5d-44fe-98e7-4052dc113d53'	System	22 Oct 2020 22:45:33
User entered 'None (0)'	System	22 Oct 2020 22:45:33

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-22T15:45:13', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '90e5eb72-4c5d-44fe-98e7-4052dc113d53'	System	22 Oct 2020 22:45:33
User entered 'None (0)'	System	22 Oct 2020 22:45:33

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-22T15:45:17', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '90e5eb72-4c5d-44fe-98e7-4052dc113d53'	System	22 Oct 2020 22:45:33
User entered 'None (0)'	System	22 Oct 2020 22:45:33



**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-22T15:45:19', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '90e5eb72-4c5d-44fe-98e7-4052dc113d53'	System	22 Oct 2020 22:45:33
User entered 'None (0)'	System	22 Oct 2020 22:45:33

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-22T15:45:25', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '90e5eb72-4c5d-44fe-98e7-4052dc113d53'	System	22 Oct 2020 22:45:33
User entered 'No (N)'	System	22 Oct 2020 22:45:33

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-22T15:45:28', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '90e5eb72-4c5d-44fe-98e7-4052dc113d53'	System	22 Oct 2020 22:45:33
User entered '22 Oct 2020 15:45'	System	22 Oct 2020 22:45:33

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '22 Oct 2020 15:27'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '22 Oct 2020 17:57'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T03:03:57', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '2288ad73-bb59-478b-afc3-02a3ab5b879e'	System	23 Oct 2020 10:04:25
User entered 'None (0)'	System	23 Oct 2020 10:04:25

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T03:04:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '2288ad73-bb59-478b-afc3-02a3ab5b879e'	System	23 Oct 2020 10:04:25
User entered 'None (0)'	System	23 Oct 2020 10:04:25



US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T03:04:02', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '2288ad73-bb59-478b-afc3-02a3ab5b879e'	System	23 Oct 2020 10:04:25
User entered 'None (0)'	System	23 Oct 2020 10:04:25

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T03:04:05', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '2288ad73-bb59-478b-afc3-02a3ab5b879e'	System	23 Oct 2020 10:04:25
User entered 'None (0)'	System	23 Oct 2020 10:04:25

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T03:04:07', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '2288ad73-bb59-478b-afc3-02a3ab5b879e'	System	23 Oct 2020 10:04:25
User entered 'None (0)'	System	23 Oct 2020 10:04:25

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T03:04:10', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '2288ad73-bb59-478b-afc3-02a3ab5b879e'	System	23 Oct 2020 10:04:25
User entered 'None (0)'	System	23 Oct 2020 10:04:25

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T03:04:12', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '2288ad73-bb59-478b-afc3-02a3ab5b879e'	System	23 Oct 2020 10:04:25
User entered 'No (N)'	System	23 Oct 2020 10:04:25

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T03:04:16', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '2288ad73-bb59-478b-afc3-02a3ab5b879e'	System	23 Oct 2020 10:04:25
User entered '23 Oct 2020 03:04'	System	23 Oct 2020 10:04:25

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '22 Oct 2020 18:52'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:22:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 22:33:56



US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 2'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:32:28', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '673cfcef-3463-4581-b884-812a222ce406'	System	24 Oct 2020 01:32:58
User entered 'None (0)'	System	24 Oct 2020 01:32:58

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:32:31', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '673cfcef-3463-4581-b884-812a222ce406'	System	24 Oct 2020 01:32:58
User entered 'None (0)'	System	24 Oct 2020 01:32:58

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:32:33', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '673cfcef-3463-4581-b884-812a222ce406'	System	24 Oct 2020 01:32:58
User entered 'None (0)'	System	24 Oct 2020 01:32:58

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:32:36', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '673cfcef-3463-4581-b884-812a222ce406'	System	24 Oct 2020 01:32:58
User entered 'None (0)'	System	24 Oct 2020 01:32:58

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:32:38', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '673cfcef-3463-4581-b884-812a222ce406'	System	24 Oct 2020 01:32:58
User entered 'None (0)'	System	24 Oct 2020 01:32:58

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:32:43', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '673cfcef-3463-4581-b884-812a222ce406'	System	24 Oct 2020 01:32:58
User entered 'None (0)'	System	24 Oct 2020 01:32:58

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:32:49', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '673cfcef-3463-4581-b884-812a222ce406'	System	24 Oct 2020 01:32:58
User entered 'No (N)'	System	24 Oct 2020 01:32:58



**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-23T18:32:53', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '673cfcef-3463-4581-b884-812a222ce406'	System	24 Oct 2020 01:32:58
User entered '23 Oct 2020 18:32'	System	24 Oct 2020 01:32:58

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 3'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:04:32', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ffe215cb-fb85-4ec1-9fb1-e711ef1d8f87'	System	25 Oct 2020 01:05:00
User entered 'None (0)'	System	25 Oct 2020 01:05:00

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:04:36', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ffe215cb-fb85-4ec1-9fb1-e711ef1d8f87'	System	25 Oct 2020 01:05:00
User entered 'None (0)'	System	25 Oct 2020 01:05:00

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:04:39', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ffe215cb-fb85-4ec1-9fb1-e711ef1d8f87'	System	25 Oct 2020 01:05:00
User entered 'None (0)'	System	25 Oct 2020 01:05:00

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:22:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:04:41', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ffe215cb-fb85-4ec1-9fb1-e711ef1d8f87'	System	25 Oct 2020 01:05:00
User entered 'None (0)'	System	25 Oct 2020 01:05:00



**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:04:43', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ffe215cb-fb85-4ec1-9fb1-e711ef1d8f87'	System	25 Oct 2020 01:05:00
User entered 'None (0)'	System	25 Oct 2020 01:05:00

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:04:46', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ffe215cb-fb85-4ec1-9fb1-e711ef1d8f87'	System	25 Oct 2020 01:05:00
User entered 'None (0)'	System	25 Oct 2020 01:05:00

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:04:53', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ffe215cb-fb85-4ec1-9fb1-e711ef1d8f87'	System	25 Oct 2020 01:05:00
User entered 'No (N)'	System	25 Oct 2020 01:05:00

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-24T18:04:57', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ffe215cb-fb85-4ec1-9fb1-e711ef1d8f87'	System	25 Oct 2020 01:05:00
User entered '24 Oct 2020 18:04'	System	25 Oct 2020 01:05:00

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 4'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-25T18:02:56', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '704456cc-1750-4367-a781-b97f6defd251'	System	26 Oct 2020 01:03:20
User entered 'None (0)'	System	26 Oct 2020 01:03:20



US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-25T18:02:59', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '704456cc-1750-4367-a781-b97f6defd251'	System	26 Oct 2020 01:03:20
User entered 'None (0)'	System	26 Oct 2020 01:03:20

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-25T18:03:01', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '704456cc-1750-4367-a781-b97f6defd251'	System	26 Oct 2020 01:03:20
User entered 'None (0)'	System	26 Oct 2020 01:03:20

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-25T18:03:02', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '704456cc-1750-4367-a781-b97f6defd251'	System	26 Oct 2020 01:03:20
User entered 'None (0)'	System	26 Oct 2020 01:03:20

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-25T18:03:04', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '704456cc-1750-4367-a781-b97f6defd251'	System	26 Oct 2020 01:03:20
User entered 'None (0)'	System	26 Oct 2020 01:03:20

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-25T18:03:07', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '704456cc-1750-4367-a781-b97f6defd251'	System	26 Oct 2020 01:03:20
User entered 'None (0)'	System	26 Oct 2020 01:03:20

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-25T18:03:12', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '704456cc-1750-4367-a781-b97f6defd251'	System	26 Oct 2020 01:03:20
User entered 'No (N)'	System	26 Oct 2020 01:03:20

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-25T18:03:15', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '704456cc-1750-4367-a781-b97f6defd251'	System	26 Oct 2020 01:03:20
User entered '25 Oct 2020 18:03'	System	26 Oct 2020 01:03:20

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 22:33:56



**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 5'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-26T18:04:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '08244e4f-d205-4377-bc85-53d864a0b7fe'	System	27 Oct 2020 01:04:21
User entered 'None (0)'	System	27 Oct 2020 01:04:21

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-26T18:04:01', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '08244e4f-d205-4377-bc85-53d864a0b7fe'	System	27 Oct 2020 01:04:21
User entered 'None (0)'	System	27 Oct 2020 01:04:21

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-26T18:04:03', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '08244e4f-d205-4377-bc85-53d864a0b7fe'	System	27 Oct 2020 01:04:21
User entered 'None (0)'	System	27 Oct 2020 01:04:21

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-26T18:04:05', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '08244e4f-d205-4377-bc85-53d864a0b7fe'	System	27 Oct 2020 01:04:21
User entered 'None (0)'	System	27 Oct 2020 01:04:21

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-26T18:04:07', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '08244e4f-d205-4377-bc85-53d864a0b7fe'	System	27 Oct 2020 01:04:21
User entered 'None (0)'	System	27 Oct 2020 01:04:21

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-26T18:04:09', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '08244e4f-d205-4377-bc85-53d864a0b7fe'	System	27 Oct 2020 01:04:21
User entered 'None (0)'	System	27 Oct 2020 01:04:21



US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-26T18:04:12', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '08244e4f-d205-4377-bc85-53d864a0b7fe'	System	27 Oct 2020 01:04:21
User entered 'No (N)'	System	27 Oct 2020 01:04:21

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-26T18:04:17', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '08244e4f-d205-4377-bc85-53d864a0b7fe'	System	27 Oct 2020 01:04:21
User entered '26 Oct 2020 18:04'	System	27 Oct 2020 01:04:21

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 6'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-27T18:09:13', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '206b1977-ba28-4581-9837-a247e14b2524'	System	28 Oct 2020 01:09:35
User entered 'None (0)'	System	28 Oct 2020 01:09:35

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-27T18:09:15', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '206b1977-ba28-4581-9837-a247e14b2524'	System	28 Oct 2020 01:09:35
User entered 'None (0)'	System	28 Oct 2020 01:09:35

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:22:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-27T18:09:17', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '206b1977-ba28-4581-9837-a247e14b2524'	System	28 Oct 2020 01:09:35
User entered 'None (0)'	System	28 Oct 2020 01:09:35



US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:22:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-27T18:09:19', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '206b1977-ba28-4581-9837-a247e14b2524'	System	28 Oct 2020 01:09:35
User entered 'None (0)'	System	28 Oct 2020 01:09:35

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-27T18:09:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '206b1977-ba28-4581-9837-a247e14b2524'	System	28 Oct 2020 01:09:35
User entered 'None (0)'	System	28 Oct 2020 01:09:35

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-27T18:09:22', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '206b1977-ba28-4581-9837-a247e14b2524'	System	28 Oct 2020 01:09:35
User entered 'None (0)'	System	28 Oct 2020 01:09:35

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-27T18:09:29', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '206b1977-ba28-4581-9837-a247e14b2524'	System	28 Oct 2020 01:09:35
User entered 'No (N)'	System	28 Oct 2020 01:09:35

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-27T18:09:31', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '206b1977-ba28-4581-9837-a247e14b2524' User entered '27 Oct 2020 18:09'	System	28 Oct 2020 01:09:35
	System	28 Oct 2020 01:09:35

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
Data entry locked.	System	22 Oct 2020 22:33:56
User entered 'Day 7'	System	22 Oct 2020 22:33:56



US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-28T13:38:08', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '64f2d027-ebe5-4c32-af4e-d62d93c33bec'	System	28 Oct 2020 20:38:37
User entered 'None (0)'	System	28 Oct 2020 20:38:37

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-28T13:38:10', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '64f2d027-ebe5-4c32-af4e-d62d93c33bec'	System	28 Oct 2020 20:38:37
User entered 'None (0)'	System	28 Oct 2020 20:38:37

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-28T13:38:13', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '64f2d027-ebe5-4c32-af4e-d62d93c33bec'	System	28 Oct 2020 20:38:37
User entered 'None (0)'	System	28 Oct 2020 20:38:37

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-28T13:38:15', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '64f2d027-ebe5-4c32-af4e-d62d93c33bec'	System	28 Oct 2020 20:38:37
User entered 'None (0)'	System	28 Oct 2020 20:38:37

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-28T13:38:18', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '64f2d027-ebe5-4c32-af4e-d62d93c33bec'	System	28 Oct 2020 20:38:37
User entered 'None (0)'	System	28 Oct 2020 20:38:37

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-28T13:38:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '64f2d027-ebe5-4c32-af4e-d62d93c33bec'	System	28 Oct 2020 20:38:37
User entered 'None (0)'	System	28 Oct 2020 20:38:37

US3682163

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:22:48

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 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-28T13:38:27', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '64f2d027-ebe5-4c32-af4e-d62d93c33bec'	System	28 Oct 2020 20:38:37
User entered 'No (N)'	System	28 Oct 2020 20:38:37

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-10-28T13:38:33', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '64f2d027-ebe5-4c32-af4e-d62d93c33bec'	System	28 Oct 2020 20:38:37
User entered '28 Oct 2020 13:38'	System	28 Oct 2020 20:38:37



**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:22:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:38:23
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 22:33:56

**US3682163**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	05 Nov 2020 21:44:14

US3682163

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	05 Nov 2020 21:44:32
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	05 Nov 2020 21:44:32
User entered '29 Oct 2020' reason for change: Data Entry Error	Susan Reed (b) (4)	05 Nov 2020 21:44:32
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	05 Nov 2020 21:44:14
User entered '5 Nov 2020'	System	05 Nov 2020 21:44:14
	Susan Reed (b) (4)	05 Nov 2020 21:44:14
	(b) (4)	

**US3682163**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	05 Nov 2020 21:44:14

**US3682163**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered empty.	Susan Reed (b) (4)	05 Nov 2020 21:44:14

**US3682163**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:20:15
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	05 Nov 2020 21:44:36

**US3682163**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'I'	System	05 Nov 2020 21:44:36



**US3682163**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	Susan Reed (b) (4)	05 Nov 2020 21:44:48

**US3682163**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '5 Nov 2020'	Susan Reed (b) (4)	05 Nov 2020 21:44:48

**US3682163**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Contact Made (CONTACT MADE)'	Susan Reed (b) (4)	05 Nov 2020 21:44:48

**US3682163**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered empty.	Susan Reed (b) (4)	05 Nov 2020 21:44:48

**US3682163**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	Susan Reed (b) (4)	05 Nov 2020 21:44:52

**US3682163**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'I'	System	05 Nov 2020 21:44:52

**US3682163**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	Susan Reed (b) (4)	12 Nov 2020 21:28:36

**US3682163**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '12 Nov 2020'	Susan Reed (b) (4)	12 Nov 2020 21:28:36



**US3682163**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	12 Nov 2020 21:28:36

**US3682163**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered empty.	Susan Reed (b) (4)	12 Nov 2020 21:28:36

US3682163

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Nov 2020 00:55:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 00:55:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Susan Reed (b) (4)	13 Nov 2020 00:55:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Nov 2020 21:34:59
User entered empty.	System	12 Nov 2020 21:34:59
	Susan Reed (b) (4)	12 Nov 2020 21:34:59
	(b) (4)	

**US3682163**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'I'	System	13 Nov 2020 00:55:55
User entered empty.	System	12 Nov 2020 21:34:59

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	Jesse Clark (b) (4)	19 Nov 2020 21:18:27

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '19 Nov 2020'	Jesse Clark (b) (4)	19 Nov 2020 21:18:27

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[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 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Clinic (Clinic)'	Jesse Clark (b) (4)	19 Nov 2020 21:18:27

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'VISIT3'	System	19 Nov 2020 21:18:27



**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	19 Nov 2020 21:53:59

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '19 Nov 2020'	(b) (4) Simone Riley (b) (4) (b) (4)	19 Nov 2020 21:53:59

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '12:40'	(b) (4) Simone Riley (b) (4) (b) (4)	19 Nov 2020 21:53:59

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered '19 Nov 2020 12:40'	System	19 Nov 2020 21:53:59

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '98.0' F	(b) (4) Simone Riley (b) (4) (b) (4)	19 Nov 2020 21:53:59

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Oral (Oral)'	(b) (4) Simone Riley (b) (4) (b) (4)	19 Nov 2020 21:53:59

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered empty.	(b) (4) Simone Riley (b) (4) (b) (4)	19 Nov 2020 21:53:59

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '89'	(b) (4) Simone Riley (b) (4) (b) (4)	19 Nov 2020 21:53:59



**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'bpm'	System	19 Nov 2020 21:53:59

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '18'	(b) (4) Simone Riley (b) (4) (b) (4)	19 Nov 2020 21:53:59

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'breaths/min'	System	19 Nov 2020 21:53:59

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '134'	(b) (4) Simone Riley (b) (4) (b) (4)	19 Nov 2020 21:53:59

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'mmHg'	System	19 Nov 2020 21:53:59

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '88'	(b) (4) Simone Riley (b) (4) (b) (4)	19 Nov 2020 21:53:59

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'mmHg'	System	19 Nov 2020 21:53:59

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10



**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	Jesse Clark (b) (4)	19 Nov 2020 21:18:35

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:22:48**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '19 Nov 2020'	Jesse Clark (b) (4)	19 Nov 2020 21:18:35

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 23:00:38

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:48**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 23:00:38

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered '13:02'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 23:00:38

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered '19 Nov 2020 13:02'	System	19 Nov 2020 23:00:38

**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:29:07
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	19 Nov 2020 21:54:04



**US3682163**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'I'	System	19 Nov 2020 21:54:04

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2020-11-25T10:22:12', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '95d6f832-ccbf-4843-a9ca-b76175f9308b'	System	25 Nov 2020 18:22:25
User entered 'No (N)'	System	25 Nov 2020 18:22:25

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2020-11-25T10:22:17', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '95d6f832-ccbf-4843-a9ca-b76175f9308b'	System	25 Nov 2020 18:22:25
User entered 'No (N)'	System	25 Nov 2020 18:22:25

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-11-25T10:22:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '95d6f832-ccbf-4843-a9ca-b76175f9308b' User entered '25 Nov 2020 10:22:21'	System	25 Nov 2020 18:22:25
	System	25 Nov 2020 18:22:25

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:43:26



**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2020-12-01T11:56:51', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'de03c4da-9088-4407-a3c7-e899e9db6fe8'	System	01 Dec 2020 19:57:06
User entered 'No (N)'	System	01 Dec 2020 19:57:06

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2020-12-01T11:56:57', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'de03c4da-9088-4407-a3c7-e899e9db6fe8'	System	01 Dec 2020 19:57:06
User entered 'No (N)'	System	01 Dec 2020 19:57:06

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-12-01T11:57:03', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'de03c4da-9088-4407-a3c7-e899e9db6fe8'	System	01 Dec 2020 19:57:06
User entered '01 Dec 2020 11:57:03'	System	01 Dec 2020 19:57:06

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2020-12-07T19:14:29', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '39854c81-9e60-470b-a31c-4750cb26c053'	System	08 Dec 2020 03:14:42
User entered 'No (N)'	System	08 Dec 2020 03:14:42

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2020-12-07T19:14:34', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '39854c81-9e60-470b-a31c-4750cb26c053'	System	08 Dec 2020 03:14:42
User entered 'No (N)'	System	08 Dec 2020 03:14:42



**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-12-07T19:14:38', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '39854c81-9e60-470b-a31c-4750cb26c053'	System	08 Dec 2020 03:14:42
User entered '07 Dec 2020 19:14:38'	System	08 Dec 2020 03:14:42

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2020-12-12T08:04:48', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'a3360a7d-3351-4824-9f3f-35ee04c36d35'	System	12 Dec 2020 16:05:00
User entered 'No (N)'	System	12 Dec 2020 16:05:00

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2020-12-12T08:04:50', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'a3360a7d-3351-4824-9f3f-35ee04c36d35'	System	12 Dec 2020 16:05:00
User entered 'No (N)'	System	12 Dec 2020 16:05:00

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-12-12T08:04:53', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'a3360a7d-3351-4824-9f3f-35ee04c36d35'	System	12 Dec 2020 16:05:00
User entered '12 Dec 2020 08:04:53'	System	12 Dec 2020 16:05:00

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 10:43:26



**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2020-12-19T07:23:30', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '3dc517d2-be43-4caa-9e48-d744970aa028'	System	19 Dec 2020 15:23:43
User entered 'No (N)'	System	19 Dec 2020 15:23:43

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2020-12-19T07:23:34', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '3dc517d2-be43-4caa-9e48-d744970aa028'	System	19 Dec 2020 15:23:43
User entered 'No (N)'	System	19 Dec 2020 15:23:43

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-12-19T07:23:39', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '3dc517d2-be43-4caa-9e48-d744970aa028'	System	19 Dec 2020 15:23:43
User entered '19 Dec 2020 07:23:39'	System	19 Dec 2020 15:23:43

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:43:26



**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2020-12-26T10:23:36', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'e6bf989f-dd99-4a68-9e09-de3970bc05a5'	System	26 Dec 2020 18:23:45
User entered 'No (N)'	System	26 Dec 2020 18:23:45

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2020-12-26T10:23:37', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'e6bf989f-dd99-4a68-9e09-de3970bc05a5'	System	26 Dec 2020 18:23:45
User entered 'No (N)'	System	26 Dec 2020 18:23:45

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2020-12-26T10:23:40', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'e6bf989f-dd99-4a68-9e09-de3970bc05a5'	System	26 Dec 2020 18:23:45
User entered '26 Dec 2020 10:23:40'	System	26 Dec 2020 18:23:45

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-01-02T07:25:01', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '781872f5-0978-45ca-92ab-fc947f7d67e0'	System	02 Jan 2021 15:25:15
User entered 'No (N)'	System	02 Jan 2021 15:25:15

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2021-01-02T07:25:08', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '781872f5-0978-45ca-92ab-fc947f7d67e0'	System	02 Jan 2021 15:25:15
User entered 'No (N)'	System	02 Jan 2021 15:25:15



**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-02T07:25:11', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '781872f5-0978-45ca-92ab-fc947f7d67e0'	System	02 Jan 2021 15:25:15
User entered '02 Jan 2021 07:25:11'	System	02 Jan 2021 15:25:15

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-01-09T18:07:30', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'b66b104b-c997-43e9-a42b-7a0ecd32b6ef'	System	10 Jan 2021 02:07:38
User entered 'No (N)'	System	10 Jan 2021 02:07:38

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2021-01-09T18:07:32', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'b66b104b-c997-43e9-a42b-7a0ecd32b6ef'	System	10 Jan 2021 02:07:38
User entered 'No (N)'	System	10 Jan 2021 02:07:38

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-09T18:07:36', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'b66b104b-c997-43e9-a42b-7a0ecd32b6ef' User entered '09 Jan 2021 18:07:36'	System	10 Jan 2021 02:07:38

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 10:43:26



**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-01-18T18:56:37', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '0cdcf904-88a9-4e46-8510-c271362d5c73'	System	19 Jan 2021 02:56:46
User entered 'No (N)'	System	19 Jan 2021 02:56:46

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2021-01-18T18:56:42', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '0cdcf904-88a9-4e46-8510-c271362d5c73'	System	19 Jan 2021 02:56:46
User entered 'No (N)'	System	19 Jan 2021 02:56:46

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-18T18:56:45', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '0cdcf904-88a9-4e46-8510-c271362d5c73'	System	19 Jan 2021 02:56:46
User entered '18 Jan 2021 18:56:45'	System	19 Jan 2021 02:56:46

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:43:26



**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-01-23T07:06:49', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'bde8abcc-2a23-46a6-b1d9-d1850d8071e3'	System	23 Jan 2021 15:06:57
User entered 'No (N)'	System	23 Jan 2021 15:06:57

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2021-01-23T07:06:51', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'bde8abcc-2a23-46a6-b1d9-d1850d8071e3'	System	23 Jan 2021 15:06:57
User entered 'No (N)'	System	23 Jan 2021 15:06:57

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-23T07:06:53', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'bde8abcc-2a23-46a6-b1d9-d1850d8071e3' User entered '23 Jan 2021 07:06:53'	System	23 Jan 2021 15:06:57
	System	23 Jan 2021 15:06:57

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-01-30T12:28:40', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered 'Yes (Y)'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2021-01-30T12:28:51', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered 'No (N)'	System	30 Jan 2021 20:30:12



**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-01-30T12:29:01', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered 'Yes (Y)'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:29:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered '0'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:29:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered '1'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:29:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered '1'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:29:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered '1'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:29:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered '1'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:29:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered '1'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:29:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered '1'	System	30 Jan 2021 20:30:12



**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:29:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered '1'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:29:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered '1'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:29:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered '0'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:29:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered '0'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:29:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered '1'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:29:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered '1'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:29:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered '1'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:29:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered '1'	System	30 Jan 2021 20:30:12



**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:29:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered '0'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:29:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered '0'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please 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 (5bb681d4df397bac)', Time: '2021-01-30T12:29:37', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-01-30T12:29:45', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered 'Yes (Y)'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please 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 (5bb681d4df397bac)', Time: '2021-01-30T12:29:53', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9'	System	30 Jan 2021 20:30:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-01-30T12:30:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'be33368a-5b04-4b6f-ba3a-8e9cd9f057b9' User entered '30 Jan 2021 12:30:00'	System	30 Jan 2021 20:30:12
	System	30 Jan 2021 20:30:12

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 10:43:26



**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:43:26

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-02-08T16:36:13', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered 'Yes (Y)'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2021-02-08T16:36:16', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered 'Yes (Y)'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please 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 (5bb681d4df397bac)', Time: '2021-02-08T16:44:14', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-02-08T16:44:16', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered 'Yes (Y)'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:44:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '0'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:44:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '1'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:44:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '1'	System	09 Feb 2021 00:45:32



**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:44:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '1'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:44:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '0'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:44:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '0'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:44:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '0'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:44:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '1'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:44:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '1'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:44:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '0'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:44:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '0'	System	09 Feb 2021 00:45:32



**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:44:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '1'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:44:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '0'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:44:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '1'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:44:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '0'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:44:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '0'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:44:54', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '0'	System	09 Feb 2021 00:45:32

**US3682163**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please 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 (5bb681d4df397bac)', Time: '2021-02-08T16:45:05', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Feb 2021 00:45:32

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-02-08T16:45:12', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered 'Yes (Y)'	System	09 Feb 2021 00:45:32



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please 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 (5bb681d4df397bac)', Time: '2021-02-08T16:45:15', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Feb 2021 00:45:32

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-08T16:45:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5c276c4e-3be6-40da-8506-56c98b2a3fb5'	System	09 Feb 2021 00:45:32
User entered '08 Feb 2021 16:45:21'	System	09 Feb 2021 00:45:32

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-02-16T15:06:48', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ee5641c9-95d0-4ef5-b4e1-3d7519b76716'	System	16 Feb 2021 23:11:47
User entered 'No (N)'	System	16 Feb 2021 23:11:47

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2021-02-16T15:06:53', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ee5641c9-95d0-4ef5-b4e1-3d7519b76716'	System	16 Feb 2021 23:11:47
User entered 'No (N)'	System	16 Feb 2021 23:11:47

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-16T15:07:03', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'ee5641c9-95d0-4ef5-b4e1-3d7519b76716' User entered '16 Feb 2021 15:07:03'	System	16 Feb 2021 23:11:47
	System	16 Feb 2021 23:11:47



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-02-22T07:08:42', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '998ea4df-102d-4ba5-87fb-11cca48f25cf'	System	22 Feb 2021 15:09:36
User entered 'Yes (Y)'	System	22 Feb 2021 15:09:36

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2021-02-22T07:08:57', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '998ea4df-102d-4ba5-87fb-11cca48f25cf'	System	22 Feb 2021 15:09:36
User entered 'No (N)'	System	22 Feb 2021 15:09:36

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-02-22T07:09:03', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '998ea4df-102d-4ba5-87fb-11cca48f25cf' User entered 'No (N)'	System	22 Feb 2021 15:09:36

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-02-22T07:09:13', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '998ea4df-102d-4ba5-87fb-11cca48f25cf'	System	22 Feb 2021 15:09:36
User entered 'Yes (Y)'	System	22 Feb 2021 15:09:36

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Please 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 (5bb681d4df397bac)', Time: '2021-02-22T07:09:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '998ea4df-102d-4ba5-87fb-11cca48f25cf'	System	22 Feb 2021 15:09:36
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Feb 2021 15:09:36



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-22T07:09:25', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '998ea4df-102d-4ba5-87fb-11cca48f25cf' User entered '22 Feb 2021 07:09:25'	System	22 Feb 2021 15:09:36
	System	22 Feb 2021 15:09:36

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-02-27T05:24:21', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'fb1d97d1-ed99-4b27-af72-2d2b383cbcc2'	System	27 Feb 2021 13:25:09
User entered 'No (N)'	System	27 Feb 2021 13:25:09

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2021-02-27T05:24:52', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'fb1d97d1-ed99-4b27-af72-2d2b383cbcc2'	System	27 Feb 2021 13:25:09
User entered 'No (N)'	System	27 Feb 2021 13:25:09

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-02-27T05:25:02', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'fb1d97d1-ed99-4b27-af72-2d2b383cbcc2'	System	27 Feb 2021 13:25:09
User entered '27 Feb 2021 05:25:02'	System	27 Feb 2021 13:25:09

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-03-10T13:01:54-08:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '35508b10-786b-4883-b875-a1d14c796e33'	System	10 Mar 2021 21:02:13
User entered 'No (N)'	System	10 Mar 2021 21:02:13

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2021-03-10T13:02:01-08:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '35508b10-786b-4883-b875-a1d14c796e33'	System	10 Mar 2021 21:02:13
User entered 'No (N)'	System	10 Mar 2021 21:02:13

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-03-10T13:02:07-08:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '35508b10-786b-4883-b875-a1d14c796e33'	System	10 Mar 2021 21:02:13
User entered '10 Mar 2021 13:02:07'	System	10 Mar 2021 21:02:13

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-03-13T05:12:11-08:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'fcf01dbe-0604-4e71-8059-7523cafb48de' User entered 'No (N)'	System	13 Mar 2021 13:12:23
	System	13 Mar 2021 13:12:23

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2021-03-13T05:12:16-08:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'fcf01dbe-0604-4e71-8059-7523cafb48de'	System	13 Mar 2021 13:12:23
User entered 'No (N)'	System	13 Mar 2021 13:12:23

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-03-13T05:12:19-08:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'fcf01dbe-0604-4e71-8059-7523cafb48de' User entered '13 Mar 2021 05:12:19'	System	13 Mar 2021 13:12:23
	System	13 Mar 2021 13:12:23

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-03-20T08:21:28-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c20b54ea-a4ee-43cc-a150-f3c08c4e1b8e'	System	20 Mar 2021 15:21:34
User entered 'No (N)'	System	20 Mar 2021 15:21:34

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2021-03-20T08:21:30-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c20b54ea-a4ee-43cc-a150-f3c08c4e1b8e'	System	20 Mar 2021 15:21:34
User entered 'No (N)'	System	20 Mar 2021 15:21:34



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-03-20T08:21:32-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'c20b54ea-a4ee-43cc-a150-f3c08c4e1b8e' User entered '20 Mar 2021 08:21:32'	System	20 Mar 2021 15:21:34

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-03-27T00:01:49-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '118b32f7-1101-4ec0-8b86-1630c3d11973'	System	27 Mar 2021 07:01:56
User entered 'No (N)'	System	27 Mar 2021 07:01:56

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2021-03-27T00:01:51-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '118b32f7-1101-4ec0-8b86-1630c3d11973'	System	27 Mar 2021 07:01:56
User entered 'No (N)'	System	27 Mar 2021 07:01:56

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-03-27T00:01:53-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '118b32f7-1101-4ec0-8b86-1630c3d11973'	System	27 Mar 2021 07:01:56
User entered '27 Mar 2021 00:01:53'	System	27 Mar 2021 07:01:56

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-04-04T11:53:16-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '6f6ed336-c768-4a8d-82cb-f0ad1f976a60'	System	04 Apr 2021 18:53:25
User entered 'No (N)'	System	04 Apr 2021 18:53:25

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2021-04-04T11:53:18-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '6f6ed336-c768-4a8d-82cb-f0ad1f976a60'	System	04 Apr 2021 18:53:25
User entered 'No (N)'	System	04 Apr 2021 18:53:25

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-04-04T11:53:20-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '6f6ed336-c768-4a8d-82cb-f0ad1f976a60'	System	04 Apr 2021 18:53:25
User entered '04 Apr 2021 11:53:20'	System	04 Apr 2021 18:53:25

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-04-12T07:09:41-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'abe2ba0e-afbd-4401-9252-adc8e48c8e63'	System	12 Apr 2021 14:09:51
User entered 'No (N)'	System	12 Apr 2021 14:09:51

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2021-04-12T07:09:43-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'abe2ba0e-afbd-4401-9252-adc8e48c8e63'	System	12 Apr 2021 14:09:51
User entered 'No (N)'	System	12 Apr 2021 14:09:51

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-04-12T07:09:46-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'abe2ba0e-afbd-4401-9252-adc8e48c8e63'	System	12 Apr 2021 14:09:51
User entered '12 Apr 2021 07:09:46'	System	12 Apr 2021 14:09:51

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-04-19T15:17:20-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'e7b1241e-120c-45dd-a35f-8edaa39ca730'	System	19 Apr 2021 22:17:30
User entered 'No (N)'	System	19 Apr 2021 22:17:30

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2021-04-19T15:17:21-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'e7b1241e-120c-45dd-a35f-8edaa39ca730'	System	19 Apr 2021 22:17:30
User entered 'No (N)'	System	19 Apr 2021 22:17:30



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-04-19T15:17:24-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'e7b1241e-120c-45dd-a35f-8edaa39ca730'	System	19 Apr 2021 22:17:30
User entered '19 Apr 2021 15:17:24'	System	19 Apr 2021 22:17:30

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[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 (5bb681d4df397bac)', Time: '2021-04-24T00:01:56-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5f221f2f-38a2-4c88-96dd-11e1ba77861e' User entered 'No (N)'	System	24 Apr 2021 07:02:09

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

Have you been exposed to someone with 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 (5bb681d4df397bac)', Time: '2021-04-24T00:01:58-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5f221f2f-38a2-4c88-96dd-11e1ba77861e' User entered 'No (N)'	System	24 Apr 2021 07:02:09

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-04-24T00:02:00-07:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: '5f221f2f-38a2-4c88-96dd-11e1ba77861e' User entered '24 Apr 2021 00:02:00'	System	24 Apr 2021 07:02:09
	System	24 Apr 2021 07:02:09

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:43:26



**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 10:43:26

**US3682163**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:22:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:43:26
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 10:43:26

US3682163

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:22:48

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 18:55:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-03-02T07:38:48-08:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'bee19ed6-057c-4f9f-9e2c-a52d37e0c847'	System	02 Mar 2021 15:39:03
User entered 'No (N)'	System	02 Mar 2021 15:39:03

**US3682163**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:55:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5bb681d4df397bac)', Time: '2021-03-02T07:39:00-08:00', User OID: 'PatientReportedOutcome (US3682163)', ODM File OID: 'bee19ed6-057c-4f9f-9e2c-a52d37e0c847'	System	02 Mar 2021 15:39:03
User entered '02 Mar 2021 07:39:00'	System	02 Mar 2021 15:39:03

**US3682163**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:16:48
User entered 'Yes (Y)'	Susan Reed (b) (4)	17 Dec 2020 21:06:52

**US3682163**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:16:48
User entered '17 Dec 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	17 Dec 2020 21:06:52

**US3682163**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:16:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	17 Dec 2020 21:06:52

**US3682163**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:16:48
User entered empty.	Susan Reed (b) (4)	17 Dec 2020 21:06:52



**US3682163**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:16:48
User entered 'Yes (Y)'	Susan Reed (b) (4)	17 Dec 2020 21:09:21

**US3682163**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:31:10
User entered 'I'	System	17 Dec 2020 21:09:21

**US3682163**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:13:33

**US3682163**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:13:33

**US3682163**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:13:33

**US3682163**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:13:33

**US3682163**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:13:39

**US3682163**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User entered 'I'	System	22 Jan 2021 21:13:39



**US3682163**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	17 Feb 2021 23:55:58

**US3682163**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '17 Feb 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	17 Feb 2021 23:55:58

**US3682163**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	17 Feb 2021 23:55:58

**US3682163**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	(b) (4) Mitchell Stern (b) (4) (b) (4)	17 Feb 2021 23:55:58

**US3682163**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	17 Feb 2021 23:56:03

**US3682163**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User entered 'I'	System	17 Feb 2021 23:56:03

**US3682163**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	18 Mar 2021 19:39:21

**US3682163**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '18 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	18 Mar 2021 19:39:21



**US3682163**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mitchell Stern (b) (4)	18 Mar 2021 19:39:21

**US3682163**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:22:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	(b) (4) Mitchell Stern (b) (4) (b) (4)	18 Mar 2021 19:39:21

**US3682163**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	18 Mar 2021 19:39:29

**US3682163**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:10:00
User entered 'I'	System	18 Mar 2021 19:39:29

**US3682163**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:52:02

**US3682163**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:52:02

**US3682163**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:52:02

**US3682163**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	22 Apr 2021 21:52:02



US3682163

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:52:36

US3682163

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:52:36

**US3682163**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered '13:00'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:52:36

**US3682163**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Apr 2021 13:00'	System	22 Apr 2021 21:52:36

US3682163

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:52:36

**US3682163**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:52:36

**US3682163**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:52:36

**US3682163**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered '84'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:52:36



**US3682163**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Apr 2021 21:52:36

US3682163

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered '16'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:52:36

**US3682163**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Apr 2021 21:52:36

US3682163

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered '130'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:52:36

**US3682163**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Apr 2021 21:52:36

US3682163

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered '87'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:52:36

**US3682163**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Apr 2021 21:52:36

US3682163

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:52:44



US3682163

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:52:44

US3682163

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:14:10

**US3682163**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:48**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:14:10

**US3682163**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered '13:33'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:14:10

**US3682163**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Apr 2021 13:33'	System	22 Apr 2021 22:14:10

US3682163

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	23 Apr 2021 21:59:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:52:48

**US3682163**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:22:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 21:52:48

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:22:48

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:33
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:23
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '25 Jan 2021'	Mitchell Stern (b) (4)	26 Jan 2021 01:23:02
	(b) (4)	



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:22:48

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:57:18
	(b) (4), (b) (6)	
User closed query 'Unable to locate this time in source document. Please review and verify accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 23:57:05
Query 'Unable to locate this time in source document. Please review and verify accordingly.' answered with 'data verified as present and correct in source' (Site from CRA).	Mitchell Stern (b) (4)	19 Apr 2021 22:55:27
	(b) (4)	
User opened query 'Unable to locate this time in source document. Please review and verify accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 23:14:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '11:30'	Mitchell Stern (b) (4)	26 Jan 2021 01:23:02
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:22:48

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:33
User entered '25 Jan 2021 11:30'	System	26 Jan 2021 01:23:02

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:22:48

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:33
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:25
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Safety Call (Safety Call)'	Mitchell Stern (b) (4)	26 Jan 2021 01:23:02
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:22:48

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:33
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:27
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	26 Jan 2021 01:23:02
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Day 1 (Day 1)'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '23 Jan 2021'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
User entered '%'	System	26 Jan 2021 01:25:59

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:22:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:25:59
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Day 2 (Day 2)'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '24 Jan 2021'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
User entered '%'	System	26 Jan 2021 01:27:15

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Moderate (Moderate)'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Moderate (Moderate)'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:22:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:27:15
	(b) (4)	



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Day 3 (Day 3)'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '25 Jan 2021'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
User entered '%'	System	26 Jan 2021 01:28:30

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:22:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 01:28:30
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 22:49:05



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '96'	(b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
User entered '%'	System	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '98.2' F	(b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	26 Jan 2021 22:49:05



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 22:49:05



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:22:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	26 Jan 2021 22:49:05

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '27 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '98'	(b) (4), (b) (6)	27 Jan 2021 23:59:00



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
User entered '%'	System	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '97.0' F	(b) (4), (b) (6)	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	27 Jan 2021 23:59:00



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
	(b) (4)	
	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:13:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 00:00:37
	(b) (4)	
User closed query 'This is stated as "none" per source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 23:58:35
	(b) (4)	
Query 'This is stated as "none" per source document. Please verify and update accordingly.' answered with 'updated as "mild," per source' (Site from CRA).	Mitchell Stern (b) (4)	19 Apr 2021 22:44:39
Signature has been broken.	(b) (4)	
	Mitchell Stern (b) (4)	19 Apr 2021 22:43:43
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Per Query Resolution	Mitchell Stern (b) (4)	19 Apr 2021 22:43:43
	(b) (4)	
User opened query 'This is stated as "none" per source document. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 23:19:19
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 23:18:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	27 Jan 2021 23:59:00
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	27 Jan 2021 23:59:00



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:22:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	27 Jan 2021 23:59:00

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '28 Jan 2021'	(b) (4), (b) (6)	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '97'	(b) (4), (b) (6)	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
User entered '%'	System	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '97.8' F	(b) (4), (b) (6)	29 Jan 2021 00:08:27



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
	(b) (4)	
	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	22 Apr 2021 21:13:15
	(b) (4)	
User closed query "This is "mild" in source document. Please verify and update accordingly." (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 00:03:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 00:01:33
	(b) (4)	
Query "This is "mild" in source document. Please verify and update accordingly." answered with 'updated per source' (Site from CRA).	Mitchell Stern (b) (4)	19 Apr 2021 22:46:12
	(b) (4)	
Signature has been broken.	Mitchell Stern (b) (4)	19 Apr 2021 22:45:51
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Per Query Resolution	Mitchell Stern (b) (4)	19 Apr 2021 22:45:51
	(b) (4)	
User opened query "This is "mild" in source document. Please verify and update accordingly." (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 23:20:56
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 23:20:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	29 Jan 2021 00:08:27
	(b) (4)	

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	29 Jan 2021 00:08:27



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	29 Jan 2021 00:08:27

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:22:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:14:52
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	29 Jan 2021 00:08:27



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:22:48

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:21:22
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '26 Jan 2021'	(b) (4), (b) (6)	29 Jan 2021 17:57:09

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:22:48

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:21:22
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Jan 2021 17:57:09

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:22:48

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:21:22
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Jan 2021 17:57:09

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:22:48

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:21:22
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '26 Jan 2021'	(b) (4), (b) (6)	29 Jan 2021 17:57:09

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:22:48

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:21:22
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	29 Jan 2021 17:57:09

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:22:48

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:21:22
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 17:57:09

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:22:48

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:21:22
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Jan 2021 17:57:09

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:22:48

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:21:22
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 17:57:09



US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:22:48

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:21:22
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 17:57:09

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:22:48

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:43
User entered '0'	System	29 Jan 2021 17:57:09

US3682163

Folder: Covid-19 Assessment 25 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:22:48

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:55:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:21:32
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Jan 2021 20:12:41

**US3682163**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	28 Jan 2021 19:12:11

**US3682163**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 19:12:11

**US3682163**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '28 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 19:12:11

**US3682163**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	28 Jan 2021 19:12:11

US3682163

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:22:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Jan 2021 17:58:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 17:58:53
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	29 Jan 2021 17:58:53
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 19:12:11
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 19:12:11



**US3682163**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 19:12:11

**US3682163**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	28 Jan 2021 19:12:11

US3682163

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:22:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Jan 2021 17:58:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 17:58:53
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	29 Jan 2021 17:58:53
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 19:12:11
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 19:12:11

**US3682163**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 19:12:11

**US3682163**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	28 Jan 2021 19:12:11

US3682163

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:22:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Jan 2021 17:58:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 17:58:53
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	29 Jan 2021 17:58:53
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 19:12:11
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 19:12:11

**US3682163**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 19:12:11

**US3682163**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:22:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	28 Jan 2021 19:12:11



US3682163

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:22:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Jan 2021 17:58:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 17:58:53
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	29 Jan 2021 17:58:53
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 19:12:11
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 19:12:11

**US3682163**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:22:48**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 19:12:11

**US3682163**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	28 Jan 2021 19:12:11

US3682163

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:22:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Jan 2021 17:58:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 17:58:53
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	29 Jan 2021 17:58:53
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 19:12:11
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 19:12:11

**US3682163**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 19:12:11

**US3682163**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	28 Jan 2021 19:12:11

US3682163

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:22:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Jan 2021 17:58:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 17:58:53
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	29 Jan 2021 17:58:53
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 19:12:11
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 19:12:11

**US3682163**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 19:12:11



US3682163

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:21:49
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 22:27:27

US3682163

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:21:49
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '26 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 22:27:27

US3682163

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:21:49
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Jan 2021 22:27:27

**US3682163**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:52
User entered 'SICKD1'	System	26 Jan 2021 22:27:27

US3682163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:22:02
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 23:45:05

US3682163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:22:06
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '26 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 23:45:05

**US3682163**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:22:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '11:25'	(b) (4), (b) (6)	26 Jan 2021 23:45:05

**US3682163**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02
User entered '26 Jan 2021 11:25'	System	26 Jan 2021 23:45:05



US3682163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:22:11
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '66' in	(b) (4), (b) (6)	26 Jan 2021 23:45:05
DataPoint set to visible.	System	26 Jan 2021 22:27:27

US3682163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:22:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered missing code ND - Not Done.	(b) (4), (b) (6)	26 Jan 2021 23:45:05
DataPoint set to visible.	System	26 Jan 2021 22:27:27

US3682163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:22:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '97.6' F	(b) (4), (b) (6)	26 Jan 2021 23:45:05

**US3682163**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:22:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Jan 2021 23:45:05

US3682163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:22:20
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 23:45:05

US3682163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:22:26
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '85'	(b) (4), (b) (6)	26 Jan 2021 23:45:05

**US3682163**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02
User entered 'bpm'	System	26 Jan 2021 23:45:05

US3682163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:22:30
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '14'	(b) (4), (b) (6)	26 Jan 2021 23:45:05



**US3682163**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02
User entered 'breaths/min'	System	26 Jan 2021 23:45:05

US3682163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:22:34
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '124'	(b) (4), (b) (6)	26 Jan 2021 23:45:05

**US3682163**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02
User entered 'mmHg'	System	26 Jan 2021 23:45:05

US3682163

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:22:36
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '86'	(b) (4), (b) (6)	26 Jan 2021 23:45:05

**US3682163**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02
User entered 'mmHg'	System	26 Jan 2021 23:45:05

**US3682163**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02

**US3682163**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:22:48**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:02

US3682163

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:22:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 23:45:15



US3682163

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:22:44
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '26 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 23:45:15

US3682163

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:22:48

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:22:49
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 22:27:37

US3682163

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:22:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:02:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:22:49
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '26 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 22:27:37

**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	13 Jan 2021 19:17:35

**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '13 Jan 2021'	(b) (4) Simone Riley (b) (4) (b) (4)	13 Jan 2021 19:17:35

**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[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 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Clinic (Clinic)'	(b) (4) Simone Riley (b) (4) (b) (4)	13 Jan 2021 19:17:35

**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:22:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 19:17:35

US3682163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:22:48

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4)	04 Feb 2021 18:57:09
User entered '6 Jan 2021' reason for change: Data Entry Error	Simone Riley (b) (4)	25 Jan 2021 21:58:01
User entered '13 Jan 2021'	(b) (4)	13 Jan 2021 19:17:55



**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:48**

[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 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:58:14

**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:48**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	(b) (4) Simone Riley (b) (4) (b) (4)	13 Jan 2021 19:17:55

**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:48**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
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 19:58:14

US3682163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:22:48

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '13 Jan 2021'	(b) (4) Simone Riley (b) (4) (b) (4)	13 Jan 2021 19:17:55

US3682163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:22:48

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Simone Riley (b) (4) (b) (4)	13 Jan 2021 19:17:55

**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:48**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 15:34:21
User entered 'mRNA-1273 (mRNA-1273)'	Simone Riley (b) (4)	13 Jan 2021 19:17:55
	(b) (4)	

**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:48**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 15:34:21
User entered 'mRNA-1273 (mRNA-1273)'	Simone Riley (b) (4)	13 Jan 2021 19:17:55
	(b) (4)	

**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:48**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	(b) (4) Simone Riley (b) (4) (b) (4)	13 Jan 2021 19:17:55



**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:48**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	13 Jan 2021 19:17:55

**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:22:48**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered empty.	System	13 Jan 2021 19:17:55

**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:21

**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:48**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:21

**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '11:01'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:21

**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:22:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '13 Jan 2021 11:01'	System	13 Jan 2021 20:37:21

US3682163

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:22:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 20:37:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 20:37:42
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 20:37:23
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:37:23

**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:22:48**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:42
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:37:23



**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:22:48**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '11:04' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:37:42
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:37:23

**US3682163**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:22:48**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:53:38
User entered '13 Jan 2021 11:04'	System	13 Jan 2021 20:37:42
User entered empty.	System	13 Jan 2021 20:37:23

US3682163

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:22:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:13:21
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:46
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 131, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 15:05:40
Query 'Per DM CLR: Per Safety Follow Up Diary Day 131, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'AE page updated accordingly' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	30 Mar 2021 16:24:47
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 131, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 08:49:08

US3682163

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:22:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Day 138 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' canceled (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 08:43:14
User opened query 'Per DM CLR: Per Day 138 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 05:25:57
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:18:36
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 18:35:01

US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:48

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:40:52
Un-reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:40:50
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:40:07
Un-reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:39:28
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:14:58
User entered 'USA-US081-2021-mRNA-1273-P301000008'	System	04 Feb 2021 19:14:53
User entered 'New'	(b) (4), (b) (6)	04 Feb 2021 19:14:53

US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User coded data point as SOC: Renal and urinary disorders, HLGT: Nephropathies, HLT: Nephritis NEC, PT: Nephritis, LLT: Nephritis - version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 00:40:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 00:40:52
User signature succeeded.	(b) (4)	
	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 18:41:39
User entered 'Right nephritis'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	



US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered '2 Feb 2021'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 18:41:32

US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	03 Mar 2021 00:48:42
Signature has been broken.	Mitchell Stern (b) (4)	03 Mar 2021 00:48:42
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4)	03 Mar 2021 00:48:42
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	03 Mar 2021 00:48:19
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:10:24
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date to condition added.' (Site from Safety).	Mitchell Stern (b) (4)	03 Mar 2021 00:49:00
	(b) (4)	
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	03 Mar 2021 00:48:42
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	03 Mar 2021 00:48:42
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	03 Mar 2021 00:48:19
Signature has been broken.	Mitchell Stern (b) (4)	03 Mar 2021 00:48:19
	(b) (4)	
User entered '11 Feb 2021' reason for change: New Information	Mitchell Stern (b) (4)	03 Mar 2021 00:48:19
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 20:16:02
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 18:41:32



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	03 Feb 2021 18:43:21
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	03 Feb 2021 18:42:52
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	04 Feb 2021 04:30:49
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Admission date reported' (Site from System).	Jesse Clark (b) (4)	03 Feb 2021 19:47:38
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		03 Feb 2021 18:43:21
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		03 Feb 2021 18:43:21
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	03 Feb 2021 18:43:21
User entered '1' reason for change: New Information	Mitchell Stern (b) (4)	03 Feb 2021 18:43:21
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	03 Feb 2021 18:42:52
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		03 Feb 2021 18:42:52

US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	03 Feb 2021 18:42:52
User entered '0' reason for change: Data Entry Error	Mitchell Stern (b) (4)	03 Feb 2021 18:42:52
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) System	03 Feb 2021 18:41:32
User entered '1'	Mitchell Stern (b) (4) (b) (4)	03 Feb 2021 18:41:32

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered '2 Feb 2021'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User closed query 'Per CDM:Kindly consider to update the data once available.Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:41:38
Query 'Per CDM:Kindly consider to update the data once available.Thank you.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 22:24:49
Signature has been broken.	(b) (4), (b) (6)	12 Feb 2021 22:24:36
User entered '03 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 22:24:36
User opened query 'Per CDM:Kindly consider to update the data once available.Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 04:31:39
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
User entered empty.	(b) (4) Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	



US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:48

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Signature has been broken.	Mitchell Stern (b) (4)	03 Mar 2021 01:15:50
	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'I'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'I'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:10:18
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated accordingly' (Site from Safety).	Mitchell Stern (b) (4)	03 Mar 2021 00:49:21
	(b) (4)	
Signature has been broken.	Mitchell Stern (b) (4)	03 Mar 2021 00:48:42
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Mitchell Stern (b) (4)	03 Mar 2021 00:48:42
	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 20:15:43
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	03 Feb 2021 18:41:32
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User closed query 'Per DM CLR: Narrative = PT PRESENTED WITH CHILLS, COUGH, AND GENERALIZED PAIN ON HOSPITAL ADMISSION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:04:16
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:10:14
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:10:10
Query 'Per DM CLR: Narrative = PT PRESENTED WITH CHILLS, COUGH, AND GENERALIZED PAIN ON HOSPITAL ADMISSION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Symptoms reviewed. Symptoms attributable to right nephritis and sequela of symptoms from recent illness (illness visit on 25JAN2021).' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	03 Mar 2021 01:11:23
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'No COVID testing results available in records.' (Site from Safety).	Mitchell Stern (b) (4) (b) (4)	03 Mar 2021 01:02:55

US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:48

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Updated accordingly' (Site from Safety). Signature has been broken.	Mitchell Stern (b) (4)	03 Mar 2021 01:02:24
	Mitchell Stern (b) (4)	03 Mar 2021 01:01:32
User entered 'PT PRESENTED WITH CHILLS, COUGH, AND GENERALIZED PAIN ON HOSPITAL ADMISSION. ON 2/2/21 (PRIOR TO THE HOSPITAL ADMISSION), THE PT SAID THAT A CXR, COVID PCR TEST, AND AN EKG HAD BEEN PERFORMED. PT IS RECEIVING PAIN MEDICATIONS IN THE HOSPITAL, BUT SHE CANNOT RECALL ANY ANTIBIOTICS ADMINISTERED. THE PT SAID THAT SHE WILL BE GETTING A RIGHT SIDED STENT SOON. A RELEASE OF INFORMATION FORM WAS SENT TO THE PT ON 2/3/21.	Mitchell Stern (b) (4)	03 Mar 2021 01:01:32
From hospital records: pt received a right ureteral stent on 2/3/21. Lab and diagnostic test results were not received within requested medical records.'		
reason for change: Data Entry Error		
User opened query 'Per DM CLR: Narrative = PT PRESENTED WITH CHILLS, COUGH, AND GENERALIZED PAIN ON HOSPITAL ADMISSION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 06:39:10
Query 'PV Query: Please request hospital discharge summary.' canceled (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 22:14:14
User opened query 'PV Query: Please request hospital discharge summary.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 20:16:43

US3682163

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:48

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 20:16:35
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 20:16:24
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
User entered 'Pt presented with chills, cough, and generalized pain on hospital admission. On 2/2/21 (prior to the hospital admission), the pt said that a CXR, COVID PCR test, and an EKG had been performed. Pt is receiving pain medications in the hospital, but she cannot recall any antibiotics administered. The pt said that she will be getting a right sided stent soon. A release of information form was sent to the pt on 2/3/21.'	(b) (4) Mitchell Stern (b) (4)	03 Feb 2021 18:41:32



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 18:41:32

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 18:41:32

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 18:41:32

US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:39:55
Un-reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:39:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:26
User entered	(b) (4), (b) (6)	04 Feb 2021 19:15:21
'USA-US081-2021-mRNA-1273-P301000008'		

US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Urinary tract lithiasis (excl renal), PT: Ureterolithiasis, LLT: Ureteral calculus - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 17:34:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 17:34:59
	(b) (4)	
Data point term sent to Coder	System	18 Feb 2021 19:39:22
Coding entries removed.	Mitchell Stern (b) (4)	18 Feb 2021 19:38:25
	(b) (4)	
Signature has been broken.	Mitchell Stern (b) (4)	18 Feb 2021 19:38:25
	(b) (4)	
User entered 'RIGHT Ureteral STONES' reason for change: New Information	Mitchell Stern (b) (4)	18 Feb 2021 19:38:25
	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 18:47:27
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 18:47:27
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 18:46:44
User entered 'Right Kidney stones'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	



US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered '2 Feb 2021'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 18:45:53

US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Signature has been broken.	Mitchell Stern (b) (4)	24 Mar 2021 18:37:02
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4)	24 Mar 2021 18:37:02
	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Signature has been broken.	Mitchell Stern (b) (4)	24 Mar 2021 18:37:02
	(b) (4)	
User entered '22 Mar 2021' reason for change: New Information	Mitchell Stern (b) (4)	24 Mar 2021 18:37:02
	(b) (4)	
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:48**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'AE#2: PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:13:42
User opened query 'AE#2: PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 20:08:48
User entered empty.	System	03 Feb 2021 18:45:53

US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jesse Clark (b) (4)	03 Feb 2021 19:49:22
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	



US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).		03 Feb 2021 19:50:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Jesse Clark (b) (4)	03 Feb 2021 19:50:12
	(b) (4)	
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	03 Feb 2021 19:49:22
User entered 'No (N)'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:35:03
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'medical records sent ( patient identifiers redacted)' (Site from Safety).	Mitchell Stern (b) (4)	05 Apr 2021 18:42:12
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 16:48:36
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	04 Feb 2021 04:28:21
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Admission date entered, patient currently hospitalized.' (Site from System).	Jesse Clark (b) (4)	03 Feb 2021 19:49:45

US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). User entered '1' reason for change: Data Entry Error	System	03 Feb 2021 19:49:22
	Jesse Clark (b) (4)	03 Feb 2021 19:49:22
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered '2 Feb 2021' reason for change: Data Entry Error	Jesse Clark (b) (4)	03 Feb 2021 19:49:22
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User closed query 'Per CDM:Kindly consider to update the data once available. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 12:52:33
Query 'Per CDM:Kindly consider to update the data once available. Thank you.' answered with 'Updated accordingly' (Site from DM).	Mitchell Stern (b) (4)	03 Mar 2021 01:13:20
	(b) (4)	
Signature has been broken.	Mitchell Stern (b) (4)	03 Mar 2021 01:13:05
	(b) (4)	
User entered '3 Feb 2021' reason for change: New Information	Mitchell Stern (b) (4)	03 Mar 2021 01:13:05
	(b) (4)	
User opened query 'Per CDM:Kindly consider to update the data once available. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 04:29:46
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jesse Clark (b) (4)	03 Feb 2021 19:49:22
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	



US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:48**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	



US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'I'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User closed query 'Per DM CLR: Please review response as there is a Concomitant Procedure (#4) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 06:12:03
Query 'Per DM CLR: Please review response as there is a Concomitant Procedure (#4) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated accordingly' (Site from DM).	Mitchell Stern (b) (4)	09 Mar 2021 23:52:09
	(b) (4)	
Signature has been broken.	Mitchell Stern (b) (4)	09 Mar 2021 23:51:57
	(b) (4)	
User entered '1' reason for change: Per Query Resolution	Mitchell Stern (b) (4)	09 Mar 2021 23:51:57
	(b) (4)	
User opened query 'Per DM CLR: Please review response as there is a Concomitant Procedure (#4) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:23:28
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User closed query 'AE#2: PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 17:27:58
Query 'AE#2: PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated accordingly' (Site from Safety).	Mitchell Stern (b) (4)	24 Mar 2021 18:37:16
	(b) (4)	
Signature has been broken.	Mitchell Stern (b) (4)	24 Mar 2021 18:37:02
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Mitchell Stern (b) (4)	24 Mar 2021 18:37:02
New Information	(b) (4)	
User opened query 'AE#2: PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 20:08:29
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:48**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	03 Feb 2021 19:50:25
	(b) (4)	
User entered 'Right kidney stones diagnosed upon hospital admission on 2/2/21. Pt is being treated for nephritis as an inpatient.'	Mitchell Stern (b) (4)	03 Feb 2021 18:45:53
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 19:50:12
User entered '0'	System	03 Feb 2021 18:45:53

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 18:45:53

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 19:49:22



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28

US3682163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 18:51:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 18:51:38
Data point term sent to Coder	System	24 Mar 2021 18:36:01
User closed query 'CDM Coding, please add to the text a unifying diagnosis. Alternatively split the term 'RIGHT FLANK AND ABDOMINAL PAIN' into two separate records, one of 'RIGHT FLANK PAIN' and one of 'ABDOMINAL PAIN', reporting each event with all relevant information e.g. start and stop dates etc.' (Site from System).	System	24 Mar 2021 18:35:50
Query 'CDM Coding, please add to the text a unifying diagnosis. Alternatively split the term 'RIGHT FLANK AND ABDOMINAL PAIN' into two separate records, one of 'RIGHT FLANK PAIN' and one of 'ABDOMINAL PAIN', reporting each event with all relevant information e.g. start and stop dates etc.' answered with 'terms separated accordingly' (Site from System).	Mitchell Stern (b) (4)	24 Mar 2021 18:35:50
User entered 'ABDOMINAL PAIN' reason for change: Per Query Resolution	Mitchell Stern (b) (4)	24 Mar 2021 18:35:40
User opened query 'CDM Coding, please add to the text a unifying diagnosis. Alternatively split the term 'RIGHT FLANK AND ABDOMINAL PAIN' into two separate records, one of 'RIGHT FLANK PAIN' and one of 'ABDOMINAL PAIN', reporting each event with all relevant information e.g. start and stop dates etc.' (Site from System).	Coder Import (b) (4)	19 Mar 2021 09:00:54
Data point term sent to Coder	System	22 Feb 2021 17:59:03
Coding entries removed.	Mitchell Stern (b) (4)	22 Feb 2021 17:58:24

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2065 of 2857

US3682163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:48

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'RIGHT FLANK and abdominal PAIN'	Mitchell Stern (b) (4)	22 Feb 2021 17:58:24
reason for change: Data Entry Error	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Flank pain, LLT: Flank pain - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 18:03:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 18:03:34
Data point term sent to Coder	System	09 Feb 2021 18:03:02
User entered 'Right flank pain'	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Mitchell Stern (b) (4)	24 Mar 2021 18:35:40
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

US3682163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

US3682163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '4 Feb 2021'	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
User entered empty.	System	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Mitchell Stern (b) (4)	24 Mar 2021 18:35:40
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '22 Mar 2021' reason for change: New Information	(b) (4)	24 Mar 2021 18:35:40
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
User entered empty.	System	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

US3682163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Feb 2021 18:02:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 18:02:54
User entered 'No (N)' reason for change: Data Entry Error	Mitchell Stern (b) (4)	09 Feb 2021 18:02:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Feb 2021 18:02:46
User entered empty.	System	09 Feb 2021 18:02:46
	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

US3682163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

US3682163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

US3682163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'I'	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) Mitchell Stern (b) (4) (b) (4)	24 Mar 2021 18:35:40
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mitchell Stern (b) (4) (b) (4)	09 Feb 2021 18:02:46



US3682163

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
User entered '0'	System	09 Feb 2021 18:02:54

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28
User entered '1'	System	24 Mar 2021 18:35:40
User entered '0'	System	09 Feb 2021 18:02:46

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:28

US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 23:47:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 23:47:06
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 23:46:21
User entered 'Worsened asthma'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	



US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '29 Jan 2021'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 23:45:59

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:48**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 23:45:59



US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:48

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	



US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:48**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	



US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'I'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:48**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Pt started taking advair diskus and albuterol again. Pt was previously prescribed these medications several years ago.'	Mitchell Stern (b) (4)	17 Feb 2021 23:45:59
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Feb 2021 23:45:59

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Feb 2021 23:45:59

US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:22:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User closed query 'Per DM CLR: Please review the dates of this AE as it overlap with the dates of AE #2. Please reconcile and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 10:42:17
Query 'Per DM CLR: Please review the dates of this AE as it overlap with the dates of AE #2. Please reconcile and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify.' answered with 'The subject was re-hospitalized for the same condition. The condition was not worsened. New entry made to capture the new SAE (though it was the same unresolved condition)' (Site from DM).	Mitchell Stern (b) (4)	05 Apr 2021 18:44:14
User opened query 'Per DM CLR: Please review the dates of this AE as it overlap with the dates of AE #2. Please reconcile and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:11:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Urinary tract lithiasis (excl renal), PT: Ureterolithiasis, LLT: Ureteral calculus - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 20:02:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 20:02:45
Data point term sent to Coder	System	18 Mar 2021 20:01:21
User entered 'Right ureteral stones'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:22:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:22:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '2 Feb 2021'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 20:01:15

US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:22:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4)	24 Mar 2021 18:39:16
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '22 Mar 2021' reason for change: New Information	Mitchell Stern (b) (4)	24 Mar 2021 18:39:16
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 20:01:15

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:22:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'I'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:22:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '15 Mar 2021'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	



US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:22:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '17 Mar 2021'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:22:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:22:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:22:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:22:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:22:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'I'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'I'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:22:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Mitchell Stern (b) (4)	24 Mar 2021 18:39:16
New Information	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:22:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'PT HAD RE-HOSPITALIZATION FOR RIGHT URETERAL STONES. PT WITH CONTINUED RIGHT FLANK PAIN AND ABDOMINAL PAIN. PT HAD A RIGHT STENT RE-INSERTION ON 3/15/21. PT TO HAVE THE STENT REMOVED ON 3/22/21. HOSPITALIZATION WAS PROLONGED DUE TO THE COMPLAINT OF CHEST PAIN AND FURTHER CARDIAC WORKUP (CHEST PAIN WAS NON-CARDIAC).' reason for change: Data Entry Error	Mitchell Stern (b) (4)	18 Mar 2021 20:01:46
	(b) (4)	
User entered 'Pt had re-hospitalization for right ureteral stones. Pt with continued right flank pain and abdominal pain. Pt had a right stent re-insertion on 3/15/21. Pt to have the stent removed on 3/22/21. Hospitalization was prolonged due to the complaint of chest pain and further cardiac workup (chest pain was non-cardiac).'	Mitchell Stern (b) (4)	18 Mar 2021 20:01:15
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Mar 2021 20:01:15



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Mar 2021 20:01:15

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Mar 2021 20:01:15

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34

US3682163

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:22:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Non-cardiac chest pain, LLT: Non-cardiac chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 20:22:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 20:22:50
Data point term sent to Coder	System	18 Mar 2021 20:05:32
User entered 'Non-cardiac chest pain'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '15 Mar 2021'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56
	(b) (4)	



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
User entered empty.	System	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

US3682163

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '17 Mar 2021'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
User entered empty.	System	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:22:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

US3682163

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:22:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'l'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	18 Mar 2021 20:04:56
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:22:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Pt complained of chest pain during her 15MAR2021 to 17MAR2021 hospitalization. Cardiac workup performed, according to the pt. ROI form send to pt on 3/18/21 for medical records from the hospital'	(b) (4) Mitchell Stern (b) (4)	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
User entered '0'	System	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34
User entered 'I'	System	18 Mar 2021 20:04:56

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:34

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41

US3682163

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:22:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Flank pain, LLT: Flank pain - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 18:39:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 18:39:38
Data point term sent to Coder	System	24 Mar 2021 18:39:07
User entered 'Right flank pain'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

US3682163

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:22:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '4 Feb 2021'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
User entered empty.	System	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

US3682163

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '22 Mar 2021'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
User entered empty.	System	24 Mar 2021 18:38:22

US3682163

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:22:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

US3682163

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:22:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

US3682163

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:22:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

US3682163

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:22:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22



US3682163

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:22:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'l'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

US3682163

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:22:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
User entered '0'	System	24 Mar 2021 18:38:22



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41
User entered 'I'	System	24 Mar 2021 18:38:22

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:46:41

US3682163

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:22:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 16:32:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 16:32:11
	(b) (4)	
Data point term sent to Coder	System	30 Mar 2021 16:31:10
User entered 'COVID-like illness'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:22:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '23 Jan 2021'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 16:30:20

US3682163

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:22:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 16:30:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Mar 2021 16:30:29
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4)	30 Mar 2021 16:30:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 16:30:20
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '28 Jan 2021'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:22:48

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 16:30:20

US3682163

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:22:48

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mitchell Stern (b) (4)	30 Mar 2021 16:31:42
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:22:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:22:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:22:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:22:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:22:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:22:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'I'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

US3682163

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:22:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	



**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:45:13
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 16:30:20
	(b) (4)	

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Mar 2021 16:30:20

**US3682163**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 16:30:20

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:22:48

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:13:21
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:18
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 08:10:20
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. (Site from DM).	Jesse Clark (b) (4) (b) (4)	11 Feb 2021 22:39:16
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 11:44:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 22:24:49

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Sep 2020 22:27:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 22:27:47
Data point term sent to Coder	System	24 Sep 2020 22:26:11
User entered 'ATORVASTATIN'	(b) (4), (b) (6)	24 Sep 2020 22:25:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 22:25:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'DYSLIPIDEMIA'	(b) (4), (b) (6)	24 Sep 2020 22:25:39



**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '40'	(b) (4), (b) (6)	24 Sep 2020 22:25:39

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Sep 2020 22:25:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 22:25:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'once daily (QD)'	(b) (4), (b) (6)	24 Sep 2020 22:25:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 22:25:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Sep 2020 22:25:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 22:25:39

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '17 Sep 2002'	(b) (4), (b) (6)	24 Sep 2020 22:25:39



**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 22:25:39

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	26 Jan 2021 22:54:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 22:25:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '11 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	26 Jan 2021 22:54:15
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 22:25:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 22:25:39

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
User entered '1'	System	24 Sep 2020 22:25:39

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
User entered '1'	System	24 Sep 2020 22:25:39

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:30
User entered '804 (804)'	System	24 Sep 2020 22:25:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 22:28:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 22:28:35
	(b) (4)	
Data point term sent to Coder	System	24 Sep 2020 22:27:12
User entered 'METFORMIN'	(b) (4), (b) (6)	24 Sep 2020 22:26:15



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 22:26:15

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'DIABETES MELLITUS'	(b) (4), (b) (6)	24 Sep 2020 22:26:15

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '1000'	(b) (4), (b) (6)	24 Sep 2020 22:26:15

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Sep 2020 22:26:15

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 22:26:15

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'twice daily (BID)'	(b) (4), (b) (6)	24 Sep 2020 22:26:15

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:48

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 22:26:15

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Sep 2020 22:26:15



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 22:26:15

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '1 Sep 2001'	(b) (4), (b) (6)	24 Sep 2020 22:26:15

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 22:26:15

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 22:26:15

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 22:26:15

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 22:26:15

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Sep 2020 22:26:15

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 22:26:15



**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Sep 2020 22:26:15

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Oct 2020 15:35:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:35:35
Data point term sent to Coder	System	26 Oct 2020 18:42:14
User entered 'Ibuprofen'	Susan Reed (b) (4) (b) (4)	26 Oct 2020 18:41:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	(b) (4) Susan Reed (b) (4) (b) (4)	26 Oct 2020 18:41:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the IINJ ARM PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJ ARM PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 05:57:13
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the IINJ ARM PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJ ARM PAIN did not meet the AE reporting criteria.' answered with 'The solicited AR did not meet AE reporting criteria.' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	30 Dec 2020 22:57:12



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '200'	Susan Reed (b) (4)	26 Oct 2020 18:41:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'mg (mg)'	(b) (4) Susan Reed (b) (4) (b) (4)	26 Oct 2020 18:41:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	26 Oct 2020 18:41:17



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'as needed (PRN)'	Susan Reed (b) (4)	26 Oct 2020 18:41:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Susan Reed (b) (4)	26 Oct 2020 18:41:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Oral (ORAL)'	Susan Reed (b) (4)	26 Oct 2020 18:41:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	(b) (4) Susan Reed (b) (4) (b) (4)	26 Oct 2020 18:41:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '23 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	26 Oct 2020 18:41:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Susan Reed (b) (4)	26 Oct 2020 18:41:17

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)' reason for change: New Information	(b) (4)	
User entered 'Yes (Y)'	Susan Reed (b) (4)	29 Oct 2020 20:46:28
	(b) (4)	
	Susan Reed (b) (4)	26 Oct 2020 18:41:17
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '24 Oct 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Susan Reed (b) (4)	29 Oct 2020 20:46:28
	(b) (4)	
	Susan Reed (b) (4)	26 Oct 2020 18:41:17
	(b) (4)	



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	Susan Reed (b) (4)	26 Oct 2020 18:41:17

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
User entered empty.	System	26 Oct 2020 18:41:17

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
User entered empty.	System	26 Oct 2020 18:41:17

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:36
User entered empty.	System	26 Oct 2020 18:41:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:48

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(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: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 07:55:05
	(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 Jan 2021 07:55:05
	(b) (4)	
Data point term sent to Coder	System	26 Jan 2021 01:23:20
User entered 'Ibuprofen'	Mitchell Stern (b) (4)	26 Jan 2021 01:22:21
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	26 Jan 2021 01:22:21
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 05:22:30
' (Site from DM).		
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4), (b) (6)	01 Mar 2021 19:10:17
' answered with 'Subject was assessed for possible COVID-19 infection ' (Site from DM).		
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4), (b) (6)	25 Feb 2021 07:30:46
' (Site from DM).		
User entered 'Body aches and headache'	Mitchell Stern (b) (4) (b) (4)	26 Jan 2021 01:22:21

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '800' reason for change: New Information	Mitchell Stern (b) (4)	26 Jan 2021 17:04:55
	(b) (4)	
User entered '200'	Mitchell Stern (b) (4)	26 Jan 2021 01:22:21
	(b) (4)	



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'mg (mg)'	Mitchell Stern (b) (4)	26 Jan 2021 01:22:21
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	26 Jan 2021 01:22:21
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'as needed (PRN)'	Mitchell Stern (b) (4)	26 Jan 2021 01:22:21
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	26 Jan 2021 01:22:21
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	26 Jan 2021 01:22:21
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	26 Jan 2021 01:22:21
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '24 Jan 2021'	Mitchell Stern (b) (4)	26 Jan 2021 01:22:21
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	26 Jan 2021 01:22:21
	(b) (4)	



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	26 Jan 2021 01:22:21
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	26 Jan 2021 01:22:21
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	26 Jan 2021 01:22:21
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 01:22:21

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 01:22:21

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 01:22:21

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 22:56:57
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	26 Jan 2021 22:56:57
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	26 Jan 2021 22:55:54
User entered 'Atorvastatin'	(b) (4), (b) (6)	26 Jan 2021 22:55:16

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	26 Jan 2021 22:55:16



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	26 Jan 2021 22:55:16

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '20'	(b) (4), (b) (6)	26 Jan 2021 22:55:16

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Jan 2021 22:55:16

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 22:55:16

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:48**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Jan 2021 22:55:16

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 22:55:16

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Jan 2021 22:55:16

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 22:55:16



**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '12 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 22:55:16

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	26 Jan 2021 22:55:16

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 22:55:16

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:48**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 22:55:16

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	26 Jan 2021 22:55:16

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 22:55:16

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 22:55:16

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Jan 2021 22:55:16



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 10:55:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 10:55:12
Data point term sent to Coder	System	22 Feb 2021 19:18:44
Coding entries removed.	Mitchell Stern (b) (4)	22 Feb 2021 19:17:53
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 12:37:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 12:37:51
Data point term sent to Coder	System	09 Feb 2021 18:06:32
User entered 'Flomax'	Mitchell Stern (b) (4)	09 Feb 2021 18:05:51

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	Mitchell Stern (b) (4)	09 Feb 2021 18:05:51

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'RIGHT ureteral STONES' reason for change: New Information	Mitchell Stern (b) (4)	22 Feb 2021 19:17:53
User entered 'Right kidney stones'	Mitchell Stern (b) (4)	09 Feb 2021 18:05:51

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0.4'	Mitchell Stern (b) (4)	09 Feb 2021 18:05:51

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'mg (mg)'	Mitchell Stern (b) (4)	09 Feb 2021 18:05:51

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:05:51

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'once daily (QD)'	Mitchell Stern (b) (4)	09 Feb 2021 18:05:51

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:05:51



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	09 Feb 2021 18:05:51

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:05:51

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '4 Feb 2021'	Mitchell Stern (b) (4)	09 Feb 2021 18:05:51

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	09 Feb 2021 18:05:51

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)' reason for change: New Information	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	24 Mar 2021 18:42:30
	(b) (4)	
	Mitchell Stern (b) (4)	09 Feb 2021 18:05:51
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '22 Mar 2021' reason for change: New Information	(b) (4)	24 Mar 2021 18:42:30
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:05:51
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	Mitchell Stern (b) (4)	09 Feb 2021 18:05:51

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
User entered '1'	System	09 Feb 2021 18:05:51



**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
User entered '1'	System	09 Feb 2021 18:05:51

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:40
User entered '804 (804)'	System	09 Feb 2021 18:05:51

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Feb 2021 08:02:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Feb 2021 08:02:43
Data point term sent to Coder	System	09 Feb 2021 18:06:32
User entered 'Ciprofloxacin'	Mitchell Stern (b) (4)	09 Feb 2021 18:06:27

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	Mitchell Stern (b) (4)	09 Feb 2021 18:06:27

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Right nephritis'	Mitchell Stern (b) (4)	09 Feb 2021 18:06:27

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '500'	Mitchell Stern (b) (4)	09 Feb 2021 18:06:27

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'mg (mg)'	Mitchell Stern (b) (4)	09 Feb 2021 18:06:27

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:06:27



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'twice daily (BID)'	Mitchell Stern (b) (4)	09 Feb 2021 18:06:27

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:06:27

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	09 Feb 2021 18:06:27

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:06:27

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '4 Feb 2021'	Mitchell Stern (b) (4)	09 Feb 2021 18:06:27

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	09 Feb 2021 18:06:27

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)' reason for change: New Information	(b) (4)	17 Feb 2021 23:55:02
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	09 Feb 2021 18:06:27

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '11 Feb 2021' reason for change: New Information	(b) (4)	17 Feb 2021 23:55:02
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:06:27
	(b) (4)	



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	Mitchell Stern (b) (4)	09 Feb 2021 18:06:27

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
User entered '2'	System	09 Feb 2021 18:06:27

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
User entered '1'	System	09 Feb 2021 18:06:27

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:46
User entered '804 (804)'	System	09 Feb 2021 18:06:27

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 18:41:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 18:41:39
Data point term sent to Coder	System	24 Mar 2021 18:41:10
Coding entries removed.	Mitchell Stern (b) (4)	24 Mar 2021 18:40:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 18:09:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 18:09:33
Data point term sent to Coder	System	09 Feb 2021 18:08:34
User entered 'Norco'	Mitchell Stern (b) (4)	09 Feb 2021 18:07:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	Mitchell Stern (b) (4)	09 Feb 2021 18:07:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'RIGHT FLANK and abdominal pain'	(b) (4)	
reason for change: Data Entry Error	Mitchell Stern (b) (4)	24 Mar 2021 18:40:45
User entered 'Right flank pain'	(b) (4)	
	Mitchell Stern (b) (4)	09 Feb 2021 18:07:39
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '5/325'	Mitchell Stern (b) (4)	09 Feb 2021 18:07:39



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'mg (mg)'	Mitchell Stern (b) (4)	09 Feb 2021 18:07:39

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:07:39

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'as needed (PRN)'	Mitchell Stern (b) (4)	09 Feb 2021 18:07:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:07:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Oral (ORAL)'	Mitchell Stern (b) (4)	09 Feb 2021 18:07:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:07:39

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '4 Feb 2021'	Mitchell Stern (b) (4)	09 Feb 2021 18:07:39

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '0'	Mitchell Stern (b) (4)	09 Feb 2021 18:07:39



**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Mitchell Stern (b) (4)	24 Mar 2021 18:40:23
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	09 Feb 2021 18:07:39
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '22 Mar 2021' reason for change: New Information	(b) (4)	24 Mar 2021 18:40:23
User entered empty.	Mitchell Stern (b) (4)	09 Feb 2021 18:07:39
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'No (N)'	Mitchell Stern (b) (4)	09 Feb 2021 18:07:39

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
User entered empty.	System	09 Feb 2021 18:07:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
User entered empty.	System	09 Feb 2021 18:07:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:50
User entered empty.	System	09 Feb 2021 18:07:39

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 06:56:46
	(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 Feb 2021 06:56:46
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 23:49:22
User entered 'Advair Diskus'	Mitchell Stern (b) (4)	17 Feb 2021 23:48:40
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 23:48:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 23:48:47
User entered 'No (N)' reason for change: New Information	Mitchell Stern (b) (4)	17 Feb 2021 23:48:47
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 23:48:40
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:48:40
	(b) (4)	



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'worsened asthma'	Mitchell Stern (b) (4)	17 Feb 2021 23:48:40
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '250/50'	Mitchell Stern (b) (4)	17 Feb 2021 23:48:40
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'ug (ug)'	Mitchell Stern (b) (4)	17 Feb 2021 23:48:40
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:48:40
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'twice daily (BID)'	Mitchell Stern (b) (4)	17 Feb 2021 23:48:40
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:48:40
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Mitchell Stern (b) (4)	17 Feb 2021 23:48:40
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:48:40
	(b) (4)	



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '29 Jan 2021'	Mitchell Stern (b) (4)	17 Feb 2021 23:48:40
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	17 Feb 2021 23:48:40
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	17 Feb 2021 23:48:40
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:48:40
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	17 Feb 2021 23:48:40
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Feb 2021 23:48:40

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 23:48:40

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Feb 2021 23:48:40



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(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: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 06:54:48
	(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 Feb 2021 06:54:48
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 23:50:22
User entered 'Albuterol'	Mitchell Stern (b) (4)	17 Feb 2021 23:49:48
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	17 Feb 2021 23:49:48
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Worsened asthma'	Mitchell Stern (b) (4)	17 Feb 2021 23:49:48
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '90'	Mitchell Stern (b) (4)	17 Feb 2021 23:49:48
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'ug (ug)'	Mitchell Stern (b) (4)	17 Feb 2021 23:49:48
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:49:48
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'as needed (PRN)'	Mitchell Stern (b) (4)	17 Feb 2021 23:49:48
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:49:48
	(b) (4)	



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Mitchell Stern (b) (4)	17 Feb 2021 23:49:48
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:49:48
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '29 Jan 2021'	Mitchell Stern (b) (4)	17 Feb 2021 23:49:48
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	17 Feb 2021 23:49:48
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	17 Feb 2021 23:49:48
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:49:48
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	17 Feb 2021 23:49:48
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 23:49:48



**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 23:49:48

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 23:49:48

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:29:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:29:43
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 23:54:24
User entered 'Novolog'	Mitchell Stern (b) (4)	17 Feb 2021 23:54:15
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	17 Feb 2021 23:54:15
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Diabetes Mellitus'	Mitchell Stern (b) (4)	17 Feb 2021 23:54:15
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:48**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '10'	Mitchell Stern (b) (4)	17 Feb 2021 23:54:15
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Other (OTHER)'	Mitchell Stern (b) (4)	17 Feb 2021 23:54:15
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Units'	Mitchell Stern (b) (4)	17 Feb 2021 23:54:15
	(b) (4)	



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'other (OTHER)'	Mitchell Stern (b) (4)	17 Feb 2021 23:54:15
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:48

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'as needed and before meals'	Mitchell Stern (b) (4)	17 Feb 2021 23:54:15
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Mitchell Stern (b) (4)	17 Feb 2021 23:54:15
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:54:15
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '15 Sep 2020'	Mitchell Stern (b) (4)	17 Feb 2021 23:54:15
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	17 Feb 2021 23:54:15
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	17 Feb 2021 23:54:15
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:48**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	17 Feb 2021 23:54:15
	(b) (4)	



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	17 Feb 2021 23:54:15
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 23:54:15

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 23:54:15

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 23:54:15

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 07:34:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:34:42
Data point term sent to Coder	System	05 Apr 2021 18:23:58
User entered 'Fentanyl'	Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:23:24

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:23:24

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Right ureteral stones'	Mitchell Stern (b) (4)	05 Apr 2021 18:23:24

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:48**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '100'	Mitchell Stern (b) (4)	05 Apr 2021 18:23:24



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'ug (ug)'	Mitchell Stern (b) (4)	05 Apr 2021 18:23:24

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:23:24

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'once (ONCE)'	Mitchell Stern (b) (4)	05 Apr 2021 18:23:24

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:23:24

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Mitchell Stern (b) (4)	05 Apr 2021 18:23:24

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	(b) (4)	
	Mitchell Stern (b) (4)	05 Apr 2021 18:23:24
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	Mitchell Stern (b) (4)	05 Apr 2021 18:23:24

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '0'	Mitchell Stern (b) (4)	05 Apr 2021 18:23:24



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:23:24

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:23:24

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:23:24

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
User entered empty.	System	05 Apr 2021 18:23:24

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
User entered empty.	System	05 Apr 2021 18:23:24

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:13:57
User entered empty.	System	05 Apr 2021 18:23:24

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 04:02:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:02:37
Data point term sent to Coder	System	05 Apr 2021 18:24:58
User entered 'Propofol'	Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:24:07

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:24:07



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Right ureteral stones'	Mitchell Stern (b) (4)	05 Apr 2021 18:24:07

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:48**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '220'	Mitchell Stern (b) (4)	05 Apr 2021 18:24:07

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'mg (mg)'	Mitchell Stern (b) (4)	05 Apr 2021 18:24:07

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:48**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:24:07

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'once (ONCE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:24:07

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:24:07

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:48**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Mitchell Stern (b) (4)	05 Apr 2021 18:24:07

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:24:07



**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	Mitchell Stern (b) (4)	05 Apr 2021 18:24:07

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '0'	Mitchell Stern (b) (4)	05 Apr 2021 18:24:07

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:24:07

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:24:07

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:24:07

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
User entered empty.	System	05 Apr 2021 18:24:07

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
User entered empty.	System	05 Apr 2021 18:24:07

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:02
User entered empty.	System	05 Apr 2021 18:24:07



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 12:29:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:29:54
Data point term sent to Coder	System	05 Apr 2021 18:24:58
User entered 'Lidocaine 2%'	Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:24:46

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:24:46

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Right ureteral stones'	Mitchell Stern (b) (4)	05 Apr 2021 18:24:46

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:48**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '80'	Mitchell Stern (b) (4)	05 Apr 2021 18:24:46

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'mg (mg)'	Mitchell Stern (b) (4)	05 Apr 2021 18:24:46

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:24:46

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:48**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'once (ONCE)'	Mitchell Stern (b) (4)	05 Apr 2021 18:24:46

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:24:46



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Intravenous (INTRAVENOUS)'	Mitchell Stern (b) (4)	05 Apr 2021 18:24:46

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	(b) (4)	
	Mitchell Stern (b) (4)	05 Apr 2021 18:24:46
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:24:46

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '0'	Mitchell Stern (b) (4)	05 Apr 2021 18:24:46

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:24:46

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:24:46

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:24:46

US3682163

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
User entered empty.	System	05 Apr 2021 18:24:46



**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
User entered empty.	System	05 Apr 2021 18:24:46

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:07
User entered empty.	System	05 Apr 2021 18:24:46

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 12:31:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:31:59
Data point term sent to Coder	System	05 Apr 2021 18:27:01
User entered 'Midazolam'	Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:26:13

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:26:13

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:48**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Right ureteral stones'	Mitchell Stern (b) (4)	05 Apr 2021 18:26:13

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '2'	Mitchell Stern (b) (4)	05 Apr 2021 18:26:13

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'mg (mg)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:26:13

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:26:13



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'once (ONCE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:26:13

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:26:13

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Intravenous (INTRAVENOUS)'	Mitchell Stern (b) (4)	05 Apr 2021 18:26:13

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	(b) (4)	
	Mitchell Stern (b) (4)	05 Apr 2021 18:26:13
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:26:13

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '0'	Mitchell Stern (b) (4)	05 Apr 2021 18:26:13

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:26:13

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:26:13



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:26:13

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
User entered empty.	System	05 Apr 2021 18:26:13

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
User entered empty.	System	05 Apr 2021 18:26:13

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:12
User entered empty.	System	05 Apr 2021 18:26:13

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 05:00:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 05:00:54
Data point term sent to Coder	System	05 Apr 2021 18:27:01
User entered 'Cefazolin'	Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:26:49

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:26:49

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Right ureteral stones'	Mitchell Stern (b) (4)	05 Apr 2021 18:26:49

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '2'	Mitchell Stern (b) (4)	05 Apr 2021 18:26:49



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'g (g)'	Mitchell Stern (b) (4)	05 Apr 2021 18:26:49

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:26:49

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'once (ONCE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:26:49

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:26:49

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:48**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Intravenous (INTRAVENOUS)'	Mitchell Stern (b) (4)	05 Apr 2021 18:26:49

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:26:49

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	Mitchell Stern (b) (4)	05 Apr 2021 18:26:49

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '0'	Mitchell Stern (b) (4)	05 Apr 2021 18:26:49



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:26:49

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:26:49

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:26:49

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
User entered empty.	System	05 Apr 2021 18:26:49

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
User entered empty.	System	05 Apr 2021 18:26:49

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:19
User entered empty.	System	05 Apr 2021 18:26:49

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 04:12:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:12:48
Data point term sent to Coder	System	05 Apr 2021 18:28:02
User entered 'Ondansetron'	Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:27:22

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:27:22



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Right ureteral stones'	Mitchell Stern (b) (4)	05 Apr 2021 18:27:22

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:22:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '4'	Mitchell Stern (b) (4)	05 Apr 2021 18:27:22

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'mg (mg)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:27:22

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:27:22

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'once (ONCE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:27:22

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:27:22

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:48**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Intravenous (INTRAVENOUS)'	Mitchell Stern (b) (4)	05 Apr 2021 18:27:22

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	(b) (4)	
	Mitchell Stern (b) (4)	05 Apr 2021 18:27:22
	(b) (4)	



**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	Mitchell Stern (b) (4)	05 Apr 2021 18:27:22

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:22:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '0'	Mitchell Stern (b) (4)	05 Apr 2021 18:27:22

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:22:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:27:22

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:27:22

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:27:22

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:22:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
User entered empty.	System	05 Apr 2021 18:27:22

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:22:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
User entered empty.	System	05 Apr 2021 18:27:22

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:22:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:23
User entered empty.	System	05 Apr 2021 18:27:22



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
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.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 07:27:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:27:40
Data point term sent to Coder	System	05 Apr 2021 18:28:02
User entered 'Dexamethasone'	Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:27:59

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:27:59

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Right ureteral stones'	Mitchell Stern (b) (4)	05 Apr 2021 18:27:59

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '4'	Mitchell Stern (b) (4)	05 Apr 2021 18:27:59

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:48**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'mg (mg)'	Mitchell Stern (b) (4)	05 Apr 2021 18:27:59

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:27:59

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'once (ONCE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:27:59

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:27:59



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Intravenous (INTRAVENOUS)'	Mitchell Stern (b) (4)	05 Apr 2021 18:27:59

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:27:59

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:27:59

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '0'	Mitchell Stern (b) (4)	05 Apr 2021 18:27:59

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:27:59

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4)	
	Mitchell Stern (b) (4)	05 Apr 2021 18:27:59
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:27:59

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
User entered empty.	System	05 Apr 2021 18:27:59



US3682163

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
User entered empty.	System	05 Apr 2021 18:27:59

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:29
User entered empty.	System	05 Apr 2021 18:27:59

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 07:33:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 07:33:46
Data point term sent to Coder	System	05 Apr 2021 18:29:03
User entered 'Famotidine'	Mitchell Stern (b) (4)	05 Apr 2021 18:28:35

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:28:35

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Right ureteral stones'	Mitchell Stern (b) (4)	05 Apr 2021 18:28:35

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:22:48**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '20'	Mitchell Stern (b) (4)	05 Apr 2021 18:28:35

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'mg (mg)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:28:35

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:28:35



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'once (ONCE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:28:35

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:28:35

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:22:48**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Intravenous (INTRAVENOUS)'	Mitchell Stern (b) (4)	05 Apr 2021 18:28:35

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	(b) (4)	
	Mitchell Stern (b) (4)	05 Apr 2021 18:28:35
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:28:35

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '0'	Mitchell Stern (b) (4)	05 Apr 2021 18:28:35

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:28:35

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:28:35



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:28:35

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
User entered empty.	System	05 Apr 2021 18:28:35

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
User entered empty.	System	05 Apr 2021 18:28:35

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:32
User entered empty.	System	05 Apr 2021 18:28:35

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:31:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:31:59
Data point term sent to Coder	System	05 Apr 2021 18:30:04
User entered 'Metoclopramide'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Right ureteral stones'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '10'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:17



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'mg (mg)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:29:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:29:17

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:22:48**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'once (ONCE)'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:29:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Intravenous (INTRAVENOUS)'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	(b) (4)	
	Mitchell Stern (b) (4)	05 Apr 2021 18:29:17
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:17

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '0'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:17



**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:29:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:17

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
User entered empty.	System	05 Apr 2021 18:29:17

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
User entered empty.	System	05 Apr 2021 18:29:17

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:38
User entered empty.	System	05 Apr 2021 18:29:17

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 18:31:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 18:31:31
Data point term sent to Coder	System	05 Apr 2021 18:30:04
User entered 'Acetaminophen'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:53

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:22:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:53



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Right ureteral stones'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:53

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '1000'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:53

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'mg (mg)'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:53

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:29:53

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'once (ONCE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:29:53

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:29:53

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:22:48**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Intravenous (INTRAVENOUS)'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:53

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	(b) (4)	
	Mitchell Stern (b) (4)	05 Apr 2021 18:29:53
	(b) (4)	



**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:53

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '0'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:53

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:53

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:29:53

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:29:53

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
User entered empty.	System	05 Apr 2021 18:29:53

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
User entered empty.	System	05 Apr 2021 18:29:53

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:42
User entered empty.	System	05 Apr 2021 18:29:53



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 10:42:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 10:42:05
Data point term sent to Coder	System	05 Apr 2021 18:31:21
User entered 'Phenylephrine'	Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:30:42

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:22:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:30:42

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:22:48**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Right ureteral stones'	Mitchell Stern (b) (4)	05 Apr 2021 18:30:42

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'I'	Mitchell Stern (b) (4)	05 Apr 2021 18:30:42

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'mg (mg)'	Mitchell Stern (b) (4)	05 Apr 2021 18:30:42

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:30:42

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'once (ONCE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:30:42

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:30:42



**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:22:48**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Intravenous (INTRAVENOUS)'	Mitchell Stern (b) (4)	05 Apr 2021 18:30:42

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:30:42

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:30:42

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '0'	Mitchell Stern (b) (4)	05 Apr 2021 18:30:42

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:30:42

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:30:42

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:30:42

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
User entered empty.	System	05 Apr 2021 18:30:42



**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
User entered empty.	System	05 Apr 2021 18:30:42

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:46
User entered empty.	System	05 Apr 2021 18:30:42

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 00:11:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 00:11:43
Data point term sent to Coder	System	05 Apr 2021 18:32:25
Data point term sent to Coder	System	05 Apr 2021 18:31:22
User entered 'Albuterol'	Mitchell Stern (b) (4)	05 Apr 2021 18:31:20

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:22:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:31:20

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Right ureteral stones'	Mitchell Stern (b) (4)	05 Apr 2021 18:31:20

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '180'	Mitchell Stern (b) (4)	05 Apr 2021 18:31:20

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'ug (ug)'	Mitchell Stern (b) (4)	05 Apr 2021 18:31:20

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:31:20



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'once (ONCE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:31:20

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:31:20

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Apr 2021 18:31:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 18:31:43
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: New Information	Mitchell Stern (b) (4)	05 Apr 2021 18:31:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	05 Apr 2021 18:31:20
	Mitchell Stern (b) (4)	05 Apr 2021 18:31:20
	(b) (4)	

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	(b) (4)	
	Mitchell Stern (b) (4)	05 Apr 2021 18:31:20
	(b) (4)	

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:31:20

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:22:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '0'	Mitchell Stern (b) (4)	05 Apr 2021 18:31:20

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:22:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:31:20

US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	(b) (4) Mitchell Stern (b) (4) (b) (4)	05 Apr 2021 18:31:20



US3682163

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:00:40
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'No (N)'	Mitchell Stern (b) (4)	05 Apr 2021 18:31:20

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:22:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
User entered empty.	System	05 Apr 2021 18:31:20

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
User entered empty.	System	05 Apr 2021 18:31:20

**US3682163**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:22:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:14:49
User entered empty.	System	05 Apr 2021 18:31:20

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:22:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:13:21
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:21
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	03 Feb 2021 18:47:07

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:22:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '2 Feb 2021'	Mitchell Stern (b) (4)	03 Feb 2021 18:47:26
	(b) (4)	

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:22:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Chest X-Ray'	Mitchell Stern (b) (4)	03 Feb 2021 18:47:26
	(b) (4)	

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	03 Feb 2021 18:47:26
	(b) (4)	



US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:22:48

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	03 Feb 2021 18:47:26
	(b) (4)	

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:22:48

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '2 Feb 2021'	Mitchell Stern (b) (4)	03 Feb 2021 18:47:46

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:22:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Electrocardiogram'	Mitchell Stern (b) (4)	03 Feb 2021 18:47:46

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	03 Feb 2021 18:47:46

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:22:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	03 Feb 2021 18:47:46

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:22:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '2 Feb 2021'	Mitchell Stern (b) (4)	04 Feb 2021 18:57:55

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:22:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'CT of the abdomen'	Mitchell Stern (b) (4)	04 Feb 2021 18:57:55

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	04 Feb 2021 18:57:55



US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:22:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	04 Feb 2021 18:57:55

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:22:48

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '3 Feb 2021'	Mitchell Stern (b) (4)	18 Feb 2021 19:41:01

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:22:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'CYTOSCOPY right URETERAL STENT INSERTION' reason for change: Data Entry Error	Mitchell Stern (b) (4)	18 Feb 2021 19:42:34
User entered 'Cytoscopy Ureteral stent insertion'	Mitchell Stern (b) (4)	18 Feb 2021 19:41:01

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	18 Feb 2021 19:41:01

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:22:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	18 Feb 2021 19:41:01

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:22:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '15 Mar 2021'	Mitchell Stern (b) (4)	18 Mar 2021 19:41:18

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:22:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Cytoscopy Right ureteral stent re-insertion'	Mitchell Stern (b) (4)	18 Mar 2021 19:41:18

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	18 Mar 2021 19:41:18



US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:22:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	18 Mar 2021 19:41:18

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:22:48

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered '22 Mar 2021'	Mitchell Stern (b) (4)	24 Mar 2021 18:43:07

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:22:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Right ureteral stent removal'	Mitchell Stern (b) (4)	24 Mar 2021 18:43:07

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	24 Mar 2021 18:43:07

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:22:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
User entered empty.	Mitchell Stern (b) (4)	24 Mar 2021 18:43:07

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:22:48

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	Mitchell Stern (b) (4)	05 Apr 2021 18:21:42

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:22:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Right Lithotripsy'	Mitchell Stern (b) (4)	05 Apr 2021 18:21:42

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	05 Apr 2021 18:21:42



US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:22:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:36
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:21:42

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:22:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered '15 Mar 2021'	Mitchell Stern (b) (4)	05 Apr 2021 18:22:05

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:22:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Right ureteral stent replacement'	Mitchell Stern (b) (4)	05 Apr 2021 18:22:05

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:22:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered 'Adverse Event (AE)'	Mitchell Stern (b) (4)	05 Apr 2021 18:22:05

US3682163

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:22:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:10:57
User signature succeeded.	Jesse Clark (b) (4)	08 Apr 2021 18:02:59
User entered empty.	Mitchell Stern (b) (4)	05 Apr 2021 18:22:05

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered	System	04 Feb 2021 19:14:53
'USA-US081-2021-MRNA-1273-P301000008'		

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53



US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Jesse'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Clark'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'CA'	System	04 Feb 2021 19:14:53



**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:54:47
User entered 'US'	System	04 Feb 2021 19:15:51

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	25 Mar 2021 17:28:28
User entered '7'	System	19 Mar 2021 15:55:56
User entered '6'	System	10 Mar 2021 19:00:50
User entered '5'	System	04 Mar 2021 16:11:53
User entered '4'	System	03 Mar 2021 16:51:33
User entered '3'	System	19 Feb 2021 16:36:14
User entered '2'	System	16 Feb 2021 16:05:47
User entered '1'	System	04 Feb 2021 19:15:51

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered	System	04 Feb 2021 19:14:53
'USA-US081-2021-MRNA-1273-P301000008'		

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53



US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Jesse'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Clark'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'CA'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:54:47
User entered 'US'	System	04 Feb 2021 19:15:51

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	25 Mar 2021 17:28:28
User entered '7'	System	19 Mar 2021 15:55:56
User entered '6'	System	10 Mar 2021 19:00:50
User entered '5'	System	04 Mar 2021 16:11:53
User entered '4'	System	03 Mar 2021 16:51:33
User entered '3'	System	19 Feb 2021 16:36:14
User entered '2'	System	16 Feb 2021 16:05:47
User entered '1'	System	04 Feb 2021 19:15:51

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:22:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '04/Feb/2021 14:15'	System	04 Feb 2021 19:15:51



US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:22:48

**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)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:54:47
User entered 'I'	(b) (4), (b) (6)	04 Feb 2021 19:15:51

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered	System	04 Feb 2021 19:14:53
'USA-US081-2021-MRNA-1273-P301000008'		

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53



US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Jesse'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Clark'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'CA'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:54:47
User entered 'US'	System	04 Feb 2021 19:15:51

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	25 Mar 2021 17:28:28
User entered '7'	System	19 Mar 2021 15:55:56
User entered '6'	System	10 Mar 2021 19:00:50
User entered '5'	System	04 Mar 2021 16:11:53
User entered '4'	System	03 Mar 2021 16:51:33
User entered '3'	System	19 Feb 2021 16:36:14
User entered '2'	System	16 Feb 2021 16:05:47
User entered '1'	System	04 Feb 2021 19:15:51

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:22:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '16/Feb/2021 11:05'	System	16 Feb 2021 16:05:47

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:22:48

**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)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:35:29
User entered 'I'	(b) (4), (b) (6)	16 Feb 2021 16:05:47



**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered	System	04 Feb 2021 19:14:53
'USA-US081-2021-MRNA-1273-P301000008'		

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53



US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Jesse'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Clark'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'CA'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:54:47
User entered 'US'	System	04 Feb 2021 19:15:51

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	25 Mar 2021 17:28:28
User entered '7'	System	19 Mar 2021 15:55:56
User entered '6'	System	10 Mar 2021 19:00:50
User entered '5'	System	04 Mar 2021 16:11:53
User entered '4'	System	03 Mar 2021 16:51:33
User entered '3'	System	19 Feb 2021 16:36:14
User entered '2'	System	16 Feb 2021 16:05:47
User entered '1'	System	04 Feb 2021 19:15:51

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:22:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '19/Feb/2021 11:36'	System	19 Feb 2021 16:36:14

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:22:48

**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)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 16:11:41
User entered 'I'	(b) (4), (b) (6)	19 Feb 2021 16:36:14

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered	System	04 Feb 2021 19:14:53
'USA-US081-2021-MRNA-1273-P301000008'		



**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Jesse'	System	04 Feb 2021 19:14:53



US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Clark'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'CA'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:54:47
User entered 'US'	System	04 Feb 2021 19:15:51

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	25 Mar 2021 17:28:28
User entered '7'	System	19 Mar 2021 15:55:56
User entered '6'	System	10 Mar 2021 19:00:50
User entered '5'	System	04 Mar 2021 16:11:53
User entered '4'	System	03 Mar 2021 16:51:33
User entered '3'	System	19 Feb 2021 16:36:14
User entered '2'	System	16 Feb 2021 16:05:47
User entered '1'	System	04 Feb 2021 19:15:51

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:22:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '03/Mar/2021 11:51'	System	03 Mar 2021 16:51:33

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:22:48

**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)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 16:11:41
User entered 'I'	(b) (4), (b) (6)	03 Mar 2021 16:51:33

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered	System	04 Feb 2021 19:14:53
'USA-US081-2021-MRNA-1273-P301000008'		

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53



**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Jesse'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Clark'	System	04 Feb 2021 19:14:53



**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'CA'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:54:47
User entered 'US'	System	04 Feb 2021 19:15:51

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	25 Mar 2021 17:28:28
User entered '7'	System	19 Mar 2021 15:55:56
User entered '6'	System	10 Mar 2021 19:00:50
User entered '5'	System	04 Mar 2021 16:11:53
User entered '4'	System	03 Mar 2021 16:51:33
User entered '3'	System	19 Feb 2021 16:36:14
User entered '2'	System	16 Feb 2021 16:05:47
User entered '1'	System	04 Feb 2021 19:15:51

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:22:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '04/Mar/2021 11:11'	System	04 Mar 2021 16:11:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:22:48

**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)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 15:55:59
User entered 'I'	(b) (4), (b) (6)	04 Mar 2021 16:11:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered	System	04 Feb 2021 19:14:53
'USA-US081-2021-MRNA-1273-P301000008'		

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53



**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Jesse'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Clark'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'CA'	System	04 Feb 2021 19:14:53



US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:54:47
User entered 'US'	System	04 Feb 2021 19:15:51

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	25 Mar 2021 17:28:28
User entered '7'	System	19 Mar 2021 15:55:56
User entered '6'	System	10 Mar 2021 19:00:50
User entered '5'	System	04 Mar 2021 16:11:53
User entered '4'	System	03 Mar 2021 16:51:33
User entered '3'	System	19 Feb 2021 16:36:14
User entered '2'	System	16 Feb 2021 16:05:47
User entered '1'	System	04 Feb 2021 19:15:51

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:22:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '10/Mar/2021 14:00'	System	10 Mar 2021 19:00:50

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:22:48

**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)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 15:55:59
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 19:00:50

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered	System	04 Feb 2021 19:14:53
'USA-US081-2021-MRNA-1273-P301000008'		

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53



US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Jesse'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Clark'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'CA'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:54:47
User entered 'US'	System	04 Feb 2021 19:15:51



**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	25 Mar 2021 17:28:28
User entered '7'	System	19 Mar 2021 15:55:56
User entered '6'	System	10 Mar 2021 19:00:50
User entered '5'	System	04 Mar 2021 16:11:53
User entered '4'	System	03 Mar 2021 16:51:33
User entered '3'	System	19 Feb 2021 16:36:14
User entered '2'	System	16 Feb 2021 16:05:47
User entered '1'	System	04 Feb 2021 19:15:51

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 09:22:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '19/Mar/2021 11:55'	System	19 Mar 2021 15:55:56

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:22:48

**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)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 15:55:59
User entered 'I'	(b) (4), (b) (6)	19 Mar 2021 15:55:56

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered	System	04 Feb 2021 19:14:53
'USA-US081-2021-MRNA-1273-P301000008'		

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Yes (Y)'	System	04 Feb 2021 19:14:53



US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'No (N)'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Jesse'	System	04 Feb 2021 19:14:53

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'Clark'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 19:15:39
User entered 'CA'	System	04 Feb 2021 19:14:53

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:54:47
User entered 'US'	System	04 Feb 2021 19:15:51

**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:22:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	25 Mar 2021 17:28:28
User entered '7'	System	19 Mar 2021 15:55:56
User entered '6'	System	10 Mar 2021 19:00:50
User entered '5'	System	04 Mar 2021 16:11:53
User entered '4'	System	03 Mar 2021 16:51:33
User entered '3'	System	19 Feb 2021 16:36:14
User entered '2'	System	16 Feb 2021 16:05:47
User entered '1'	System	04 Feb 2021 19:15:51



**US3682163**

**Folder: SAE USA-US081-2021-MRNA-1273-P301000008**

**Form: Safety Report Form (8)**

**Generated On: 10 Jun 2021 09:22:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered '25/Mar/2021 13:28'	System	25 Mar 2021 17:28:28

US3682163

Folder: SAE USA-US081-2021-MRNA-1273-P301000008

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:22:48

**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)	16 Apr 2021 22:43:35
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 20:58:28
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	25 Mar 2021 17:28:28