

US3882016 (Prod: VA Greater Los Angeles Healthcare - NAVREF)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:17:29

All time stamps listed in this document are displayed in GMT

US3882016

Form: Participant Creation

Data signed: (b) (4) 05 Sep 2020 22:56:59

Generated On: 10 Jun 2021 10:17:29

Participant ID

US3882016

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

US3882016

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Sep 2020 22:56:59

Generated On: 10 Jun 2021 10:17:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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

US3882016

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Sep 2020 22:56:59

Generated On: 10 Jun 2021 10:17:29

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	56
Age Units	YEARS
Age (Derived)	57
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
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

US3882016

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Sep 2020 22:56:59

Generated On: 10 Jun 2021 10:17:29

Date of Informed Consent (*dd MMM yyyy*) 03 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input checked="" type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

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

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

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

If Yes, previous participant number _____

Enrollment Trigger 1

US3882016

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Sep 2020 22:56:59

Generated On: 10 Jun 2021 10:17:29

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3882016

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Sep 2020 22:56:59

Generated On: 10 Jun 2021 10:17:29

Were any significant conditions reported?

Yes ☒

No ☐

US3882016

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Condition	HUMAN IMMUNODEFICIENCY VIRUS INFECTION
Start date (dd MMM yyyy)	21 JUN 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3882016

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Condition	DIABETES MELLITUS
Start date (dd MMM yyyy)	16 MAR 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3882016

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Condition	PRESBYOPIA
Start date (dd MMM yyyy)	07 JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3882016

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Condition	METHAMPHETAMINE ABUSE
Start date (dd MMM yyyy)	26 MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3882016

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Condition	H/O: ATTEMPTED SUICIDE
Start date (dd MMM yyyy)	07 MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3882016

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Condition	PSYCHOTIC DISORDER WITH DELUSIONS CAUSED BY STIMULANT
Start date (dd MMM yyyy)	03 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3882016

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Condition	ADULT VICTIM OF (b) (6)
Start date (dd MMM yyyy)	15 JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3882016

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Condition	CHRONIC POST-TRAUMATIC STRESS DISORDER
Start date (dd MMM yyyy)	30 NOV 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3882016

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Condition	ALCOHOL DEPENDENCE
Start date (dd MMM yyyy)	15 AUG 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3882016

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Condition	COCAINE DEPENDENCE
Start date (dd MMM yyyy)	15 AUG 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3882016

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Condition	NICOTINE DEPENDENCE
Start date (dd MMM yyyy)	09 JUL 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3882016

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Condition	MI - MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	02 MAR 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3882016

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Condition	ARTHRITIS OF RIGHT HIP
Start date (dd MMM yyyy)	16 FEB 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3882016

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Condition	ARTHRITIS OF LEFT HIP
Start date (dd MMM yyyy)	16 FEB 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3882016

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Condition	COLOSTOMY PRESENT
Start date (dd MMM yyyy)	20 NOV 2003
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)	NOV 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3882016

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Condition	INSOMNIA
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)	

US3882016

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Sep 2020 22:56:59

Generated On: 10 Jun 2021 10:17:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:35 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 13:35
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	168 lb
BMI (<i>xxx.x</i>)	26.36754 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3882016

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 08 Sep 2020 23:10:02

Generated On: 10 Jun 2021 10:17:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 SEP 2020

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

US3882016

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Sep 2020 22:56:59

Generated On: 10 Jun 2021 10:17:29

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☒ No ☐

Specify UNEMPLOYED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3882016

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Sep 2020 22:56:59

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Sep 2020 22:56:59

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 03 Oct 2020 02:03:44

Generated On: 10 Jun 2021 10:17:29

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 145209

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 ☐

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 11 Nov 2020 00:34:16

Generated On: 10 Jun 2021 10:17:29

Height	ND - Not Done
Weight	ND - Not Done

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 11 Nov 2020 00:34:16

Generated On: 10 Jun 2021 10:17:29

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)	04 SEP 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 11:20
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 11 Nov 2020 00:34:16

Generated On: 10 Jun 2021 10:17:29

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 SEP 2020
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 12:40
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3882016

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Sep 2020 22:56:59

Generated On: 10 Jun 2021 10:17:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 SEP 2020

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

US3882016

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Sep 2020 22:56:59

Generated On: 10 Jun 2021 10:17:29

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) 04 SEP 2020

What was the treatment time? (00:00-23:59) 12:07 (24 HR)

Treatment Date and Time (derived) 04 SEP 2020 12:07

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

US3882016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Nov 2020 00:24:30

Generated On: 10 Jun 2021 10:17:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 SEP 2020

Collection time (00:00-23:59)

11:40 (24 HR)

Collection date and time (derived)

04 SEP 2020 11:40

US3882016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Sep 2020 22:56:59

Generated On: 10 Jun 2021 10:17:29

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:45	04 SEP 2020 11:45
Nasopharyngeal Swab 2	No		

US3882016

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Sep 2020 22:56:59

Generated On: 10 Jun 2021 10:17:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

04 SEP 2020 12:27

PC Close Date & Time

04 SEP 2020 14:57

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 04 SEP 2020 15:52

PC Close Date & Time 05 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:29

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

98.4 °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

05 SEP 2020 15:58

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 16:03

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:29

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 15:52

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

08 SEP 2020 15:56

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

09 SEP 2020 15:53

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:29

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 15:47

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 SEP 2020 12:27

PC Close Date & Time

04 SEP 2020 14:57

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 SEP 2020 15:52

PC Close Date & Time

05 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

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

05 SEP 2020 15:57

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

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

06 SEP 2020 16:01

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

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

07 SEP 2020 15:51

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

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

08 SEP 2020 15:55

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

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

09 SEP 2020 15:52

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

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

10 SEP 2020 15:46

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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 ☐

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

04 SEP 2020 12:27

PC Close Date & Time

04 SEP 2020 14:57

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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 ☐

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

04 SEP 2020 15:52

PC Close Date & Time

05 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

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 ☒

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 15:58
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

59 of 1956

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 16:02
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

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)

61 of 1956

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 15:50
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

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)

63 of 1956

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 15:55
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

65 of 1956

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 15:52
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

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 ☒

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 15:45
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3882016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Sep 2020 16:04:07

Generated On: 10 Jun 2021 10:17:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3882016

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Sep 2020 16:04:06

Generated On: 10 Jun 2021 10:17:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Sep 2020 00:33:51

Generated On: 10 Jun 2021 10:17:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3882016

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Sep 2020 00:33:51

Generated On: 10 Jun 2021 10:17:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Sep 2020 16:58:20

Generated On: 10 Jun 2021 10:17:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3882016

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Sep 2020 16:58:20

Generated On: 10 Jun 2021 10:17:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 03 Oct 2020 02:03:45

Generated On: 10 Jun 2021 10:17:29

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

Visit date (dd MMM yyyy)	2 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
------------	--------

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Oct 2020 02:03:45

Generated On: 10 Jun 2021 10:17:29

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)	2 OCT 2020
Time of assessment (00:00-23:59)	12:08 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 12:08
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Oct 2020 02:03:45

Generated On: 10 Jun 2021 10:17:29

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)	2 OCT 2020
Time of assessment (00:00-23:59)	13:33 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 13:33
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3882016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Oct 2020 02:03:44

Generated On: 10 Jun 2021 10:17:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 OCT 2020

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

US3882016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 03 Oct 2020 02:03:44

Generated On: 10 Jun 2021 10:17:29

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) 2 OCT 2020

What was the treatment time? (00:00-23:59) 13:03 (24 HR)

Treatment Date and Time (derived) 2 OCT 2020 13:03

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

US3882016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Oct 2020 02:03:44

Generated On: 10 Jun 2021 10:17:29

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

Collection date (dd MMM yyyy)	2 OCT 2020
-------------------------------	------------

Collection time (00:00-23:59)	12:50 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	2 OCT 2020 12:50
------------------------------------	------------------

US3882016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 03 Oct 2020 02:03:44

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 03 Oct 2020 02:03:44

Generated On: 10 Jun 2021 10:17:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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

98.3 °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

02 OCT 2020 13:38

PC Open Date & Time

02 OCT 2020 13:23

PC Close Date & Time

02 OCT 2020 15:53

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °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	03 OCT 2020 10:56
PC Open Date & Time	02 OCT 2020 16:48
PC Close Date & Time	03 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:29

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

98.7 °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 03 OCT 2020 12:01

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 12:05

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:29

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 05 OCT 2020 12:01

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

06 OCT 2020 12:00

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

07 OCT 2020 12:10

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:29

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

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

08 OCT 2020 12:02

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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

02 OCT 2020 13:38

PC Open Date & Time

02 OCT 2020 13:23

PC Close Date & Time

02 OCT 2020 15:53

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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

1

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 10:56

PC Open Date & Time

02 OCT 2020 16:48

PC Close Date & Time

03 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

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

03 OCT 2020 12:02

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

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

04 OCT 2020 12:06

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

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

05 OCT 2020 12:01

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

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

06 OCT 2020 12:00

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

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

07 OCT 2020 12:11

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

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

08 OCT 2020 12:02

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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 ☐

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 13:39
PC Open Date & Time	02 OCT 2020 13:23
PC Close Date & Time	02 OCT 2020 15:53

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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 ☐

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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

No ☒

Yes ☐

PC Time stamp	03 OCT 2020 10:57
PC Open Date & Time	02 OCT 2020 16:48
PC Close Date & Time	03 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

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 ☒

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 12:01
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

105 of 1956

EAB) (1725)

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 12:06
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

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)

107 of 1956

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 12:01
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

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

109 of 1956

EAB) (1725)

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 12:01
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

111 of 1956

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 12:11
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

113 of 1956

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 12:03
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3882016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Oct 2020 23:49:31

Generated On: 10 Jun 2021 10:17:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3882016

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 09 Oct 2020 23:49:31

Generated On: 10 Jun 2021 10:17:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Oct 2020 23:13:28

Generated On: 10 Jun 2021 10:17:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3882016

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Oct 2020 23:13:28

Generated On: 10 Jun 2021 10:17:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 30 Oct 2020 01:12:22

Generated On: 10 Jun 2021 10:17:29

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments + CHEST PAIN REQUIRING ED
VISIT ON 10/26. IMAGING AND
If Contact Not Made, please provide Comments EKG UNREMARKABLE. BLOOD
GLUCOSE >300 MG/DL.
ALOGLIPTIN PO DOSE
INCREASED BY PCP TODAY

US3882016

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 30 Oct 2020 01:12:22

Generated On: 10 Jun 2021 10:17:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 31 Oct 2020 01:21:38

Generated On: 10 Jun 2021 10:17:29

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

Visit date (dd MMM yyyy)	30 OCT 2020
--------------------------	-------------

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

Folder OID	VISIT3
------------	--------

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Oct 2020 01:21:38

Generated On: 10 Jun 2021 10:17:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 OCT 2020
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 12:15
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3882016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Oct 2020 01:21:38

Generated On: 10 Jun 2021 10:17:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 OCT 2020

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

US3882016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Oct 2020 01:21:38

Generated On: 10 Jun 2021 10:17:29

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

Collection date (dd MMM yyyy)	30 OCT 2020
-------------------------------	-------------

Collection time (00:00-23:59)	12:50 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	30 OCT 2020 12:50
------------------------------------	-------------------

US3882016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 31 Oct 2020 01:21:38

Generated On: 10 Jun 2021 10:17:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 11:12:50

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 14:53:22

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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)	<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"/>

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3882016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 02:49:22

Generated On: 10 Jun 2021 10:17:29

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments 3 ATTEMPTS WERE MADE BUT
CONTACT WAS NOT
If Contact Not Made, please provide Comments SUCCESSFUL

US3882016

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Jan 2021 04:10:25

Generated On: 10 Jun 2021 10:17:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3882016

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Jan 2021 04:10:25

Generated On: 10 Jun 2021 10:17:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882016

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 02:49:22

Generated On: 10 Jun 2021 10:17:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 JAN 2021

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

Comments DENIES FEVER, CHILLS,
COUGH, SORE THROAT,
MALAISE, HEADACHE,
OLFACTORY/GUSTATORY
CHANGES, OR N/V. DENIES
KNOWN EXPOSURE TO C19.
DENIES CHANGES IN RX LIST

If Contact Not Made, please provide Comments

US3882016

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 02:49:22

Generated On: 10 Jun 2021 10:17:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882016

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 MAR 2021

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

Comments LEFT VOICEMAIL

If Contact Not Made, please provide Comments

US3882016

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 23:05:40

Generated On: 10 Jun 2021 10:17:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882016

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

Form: Unblinding

Data signed: (b) (4) 01 Apr 2021 19:55:48

Generated On: 10 Jun 2021 10:17:29

Date of updated informed consent (dd MMM yyyy)	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	True
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input checked="" type="radio"/> Amendment 6 or later <input type="radio"/>
Date of unblinding (dd MMM yyyy)	4 MAR 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	

US3882016

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 07 Dec 2020 01:43:24

Generated On: 10 Jun 2021 10:17:29

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Mar 2021 23:11:03

Generated On: 10 Jun 2021 10:17:29

AEID

Adverse event

CHEST PAIN (GENERAL PAIN
AND DISCOMFORT)

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)

26 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

170 of 1956

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Mar 2021 23:11:03

Generated On: 10 Jun 2021 10:17:29

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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	
CHEST PAIN REQUIRING ED VISIT ON 10/26. IMAGING AND EKG UNREMARKABLE.	
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)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

171 of 1956

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Mar 2021 23:11:03

Generated On: 10 Jun 2021 10:17:29

AEID	USA-US095-2021-MRNA-1273-P30 1000003
Adverse event	ACUTE SUBSTANCE INDUCED PSYCHOSIS
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)	11 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	7 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	20 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	7 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	172 of 1956

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Mar 2021 23:11:03

Generated On: 10 Jun 2021 10:17:29

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 type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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	

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Mar 2021 23:11:03

Generated On: 10 Jun 2021 10:17:29

SUBJECT WAS TAKEN TO THE
ER ON 11/20/2020 BY VAPD
DISORGANIZED AND
MUMBLING THAT THEY WERE
GOING TO KILL THEMSELVES.
SUBJECT WAS ADMITTED FOR
AN INVOLUNTARY HOLD.
THEY WERE DISCHARGED
12/7/2020

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

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Sep 2020 16:58:20

Generated On: 10 Jun 2021 10:17:29

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

Yes ☒

No ☐

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

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication GENERAL BODY PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

176 of 1956

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

Name of Medication ASIPIRIN

Prophylaxis Yes ☒
No ☐

Indication STROKE/HEART ATTACK
PREVENTION

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

178 of 1956

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication MI - MYOCARDIAL
INFARCTION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

180 of 1956

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

Name of Medication ALOGLIPTIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 6.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

182 of 1956

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

184 of 1956

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

Name of Medication METOPROLOL SUCCINATE

Prophylaxis Yes ☐
No ☒

Indication MI - MYOCARDIAL
INFARCTION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

186 of 1956

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication MOOD (CHRONIC
POST-TRAUMATIC STRESS
DISORDER)

Dose per administration 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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

188 of 1956

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 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"/>

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication GENERAL BODY PAIN

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

190 of 1956

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

Name of Medication HYDROXYZINE

Prophylaxis Yes ☒
No ☐

Indication AS NEEDED FOR INSOMNIA

Dose per administration 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)

192 of 1956

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES

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

EVERY EVENING

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

PRODUCTION RELEASE (v12.003

194 of 1956

EAB) (1725)

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY MORNING

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

196 of 1956

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

Name of Medication QUETIAPINE FUMARATE

Prophylaxis Yes ☐
No ☒

Indication PSYCHOTIC DISORDER WITH
DELUSIONS

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

198 of 1956

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

Name of Medication SEMAGLUTIDE 0.25 MG/1.5 ML

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 0.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

200 of 1956

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

Name of Medication NALTREXONE

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL DEPENDENCE

Dose per administration 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)

202 of 1956

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 21 Apr 2021 17:38:04

Generated On: 10 Jun 2021 10:17:29

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

US3882016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Dec 2020 01:43:24

Generated On: 10 Jun 2021 10:17:29

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3882016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Feb 2021 23:26:17

Generated On: 10 Jun 2021 10:17:29

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
26 OCT 2020	EKG	Diagnostic	

US3882016

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 20 Mar 2021 23:11:03

Generated On: 10 Jun 2021 10:17:29

Date of study discontinuation/completion (dd MMM yyyy) 4 MAR 2021

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input checked="" type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify NON COMPLIANT

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 08 Feb 2021 02:49:22

Generated On: 10 Jun 2021 10:17:29

SAEID	USA-US095-2021-MRNA-1273-P301000003
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	MICHAEL
Investigator's Last Name	LEWIS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Feb 2021 02:49:22

Generated On: 10 Jun 2021 10:17:29

SAEID	USA-US095-2021-MRNA-1273-P301000003
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	MICHAEL
Investigator's Last Name	LEWIS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	02/FEB/2021 10:15
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

Audit

US3882016 (Prod: VA Greater Los Angeles Healthcare - NAVREF)

US3882016

Form: Participant Creation

Generated On: 10 Jun 2021 10:17:29

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 04:06:29
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'US3882016'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 00:19:17

US3882016

Form: Participant Creation

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46

US3882016

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:17:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 23:46:49
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:30:25

US3882016

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 23:46:51
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 00:19:18

US3882016

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 23:46:52
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Clinic (Clinic)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:30:25

US3882016

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:17:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'SCRN'	System	05 Sep 2020 20:30:25

US3882016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:29

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:26:07
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered (b) (6) 1963'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 00:19:19

US3882016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:29

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 03:24:17
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '56'	Suchi Tiwari (b) (4)	05 Sep 2020 20:36:54

US3882016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:29

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'YEARS'	System	05 Sep 2020 20:36:54

US3882016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:29

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '57'	System	05 Sep 2020 20:37:27

US3882016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:29

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:44:37
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Male (M)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:36:54

US3882016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:29

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 03:24:22
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:36:54

US3882016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:29

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 03:24:22
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '0'	Suchi Tiwari (b) (4)	05 Sep 2020 20:36:54

US3882016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:29

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 03:24:22
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'l'	Suchi Tiwari (b) (4)	05 Sep 2020 20:36:54

US3882016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:29

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 03:24:22
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '0'	Suchi Tiwari (b) (4)	05 Sep 2020 20:36:54

US3882016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:29

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 03:24:22
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '0'	Suchi Tiwari (b) (4)	05 Sep 2020 20:36:54

US3882016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:29

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 03:24:22
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '0'	Suchi Tiwari (b) (4)	05 Sep 2020 20:36:54

US3882016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 03:24:22
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '0'	Suchi Tiwari (b) (4)	05 Sep 2020 20:36:54

US3882016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:29

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 03:24:22
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:36:54

US3882016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:29

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 03:24:22
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '0'	Suchi Tiwari (b) (4)	05 Sep 2020 20:36:54

US3882016

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:29

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 03:24:22
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '0'	Suchi Tiwari (b) (4)	05 Sep 2020 20:36:54

US3882016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:29

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:46:41
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '03 Sep 2020'	Suchi Tiwari (b) (4)	05 Sep 2020 20:37:27

US3882016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'Sep 2020'	System	05 Sep 2020 20:37:27

US3882016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2020'	System	05 Sep 2020 20:37:27

US3882016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:29

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:46:41
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Amendment 3 (3)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:37:27

US3882016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:46:41
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:37:27

US3882016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:46:41
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:37:27

US3882016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:29

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:46:41
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:37:27

US3882016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:29

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:46:41
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'No (N)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:37:27

US3882016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:29

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:46:41
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 00:19:18

US3882016

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:29

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'I'	System	05 Sep 2020 20:37:34

US3882016

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:14:42
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 17:16:04
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:39:20
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Yes (Y)'	Suchi Tiwari (b) (4) (b) (4)	05 Sep 2020 20:37:34

US3882016

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:17:29

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:47:00
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:37:43

US3882016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:41:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 17:24:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:11:56
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Retroviral infections, PT: HIV infection, LLT: HIV infection - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 07:30:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 07:30:40
User signature succeeded.	Michael Lewis (b) (4)	08 Sep 2020 23:10:03
Data point term sent to Coder	System	08 Sep 2020 17:42:02
Coding entries removed.	Lauren Vigil (b) (4)	08 Sep 2020 17:41:15
User entered 'Human immunodeficiency virus infection' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Sep 2020 17:41:15
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 20:40:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 20:40:43
Data point term sent to Coder	System	05 Sep 2020 20:40:25
User entered 'Presbyopia'	Suchi Tiwari (b) (4)	05 Sep 2020 20:39:56

US3882016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:11:58
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '21 Jun 2018' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	11 Nov 2020 02:45:07
Signature has been broken.	Suchi Tiwari (b) (4)	11 Nov 2020 02:44:45
User entered '06 Jul 2020' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	11 Nov 2020 02:44:45
User signature succeeded.	Michael Lewis (b) (4)	08 Sep 2020 23:10:03
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	08 Sep 2020 17:41:15
User entered '21 Jun 2018' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Sep 2020 17:41:15
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	05 Sep 2020 20:39:56
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:39:56

US3882016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	08 Sep 2020 23:10:03
User entered '0'	Suchi Tiwari (b) (4)	05 Sep 2020 20:39:56

US3882016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	08 Sep 2020 23:10:03
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	08 Sep 2020 17:42:01
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	08 Sep 2020 17:41:15
User entered 'Yes (Y)'	Suchi Tiwari (b) (4) (b) (4)	05 Sep 2020 20:39:56

US3882016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:29

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Signature has been broken.	Lauren Vigil (b) (4)	28 Jan 2021 22:31:56
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 21:54:38
Signature has been broken.	Lauren Vigil (b) (4)	12 Dec 2020 00:05:38
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
Signature has been broken.	Lauren Vigil (b) (4)	02 Dec 2020 16:18:14
User signature succeeded.	Michael Lewis (b) (4)	08 Sep 2020 23:10:03
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:39:56

US3882016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Signature has been broken.	Lauren Vigil (b) (4)	28 Jan 2021 22:32:35
User signature succeeded.	Michael Lewis (b) (4)	08 Sep 2020 23:10:03
User entered '0' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Sep 2020 17:42:01
User entered '1' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Sep 2020 17:41:15
User entered '0'	Suchi Tiwari (b) (4)	05 Sep 2020 20:39:56

US3882016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'Jun 2018'	System	11 Nov 2020 02:45:07
User entered 'Jul 2020'	System	11 Nov 2020 02:44:45
User entered 'Jun 2018'	System	08 Sep 2020 17:41:15
User entered empty.	System	05 Sep 2020 20:39:56

US3882016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2018'	System	11 Nov 2020 02:45:07
User entered '2020'	System	11 Nov 2020 02:44:45
User entered '2018'	System	08 Sep 2020 17:41:15
User entered empty.	System	05 Sep 2020 20:39:56

US3882016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	05 Sep 2020 20:39:56

US3882016

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	05 Sep 2020 20:39:56

US3882016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	08 Sep 2020 23:10:03
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)	08 Sep 2020 17:52:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 17:52:57
Data point term sent to Coder	System	08 Sep 2020 17:51:24
User entered 'Diabetes mellitus'	Lauren Vigil (b) (4)	08 Sep 2020 17:50:46

US3882016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	08 Sep 2020 23:10:03
User entered '16 Mar 2016'	Lauren Vigil (b) (4)	08 Sep 2020 17:50:46

US3882016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	08 Sep 2020 23:10:03
User entered '0'	Lauren Vigil (b) (4)	08 Sep 2020 17:50:46

US3882016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	08 Sep 2020 23:10:03
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	08 Sep 2020 17:50:46

US3882016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	08 Sep 2020 23:10:03
User entered empty.	Lauren Vigil (b) (4)	08 Sep 2020 17:50:46

US3882016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	08 Sep 2020 23:10:03
User entered '0'	Lauren Vigil (b) (4)	08 Sep 2020 17:50:46

US3882016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'Mar 2016'	System	08 Sep 2020 17:50:46

US3882016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2016'	System	08 Sep 2020 17:50:46

US3882016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	08 Sep 2020 17:50:46

US3882016

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	08 Sep 2020 17:50:46

US3882016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:47:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:47:47
Data point term sent to Coder	System	11 Nov 2020 02:46:34
User entered 'Presbyopia'	Suchi Tiwari (b) (4)	11 Nov 2020 02:45:35

US3882016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '07 Jun 2020'	Suchi Tiwari (b) (4)	11 Nov 2020 02:45:35

US3882016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:45:35

US3882016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:45:35

US3882016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:29

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:45:35

US3882016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:45:35

US3882016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:29

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'Jun 2020'	System	11 Nov 2020 02:45:35

US3882016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2020'	System	11 Nov 2020 02:45:35

US3882016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:45:35

US3882016

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:45:35

US3882016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Drug abuse, LLT: Amphetamine abuse - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:47:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:47:48
Data point term sent to Coder	System	11 Nov 2020 02:46:33
User entered 'Methamphetamine abuse'	Suchi Tiwari (b) (4)	11 Nov 2020 02:45:55

US3882016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '26 May 2020'	Suchi Tiwari (b) (4)	11 Nov 2020 02:45:55

US3882016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:45:55

US3882016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:45:55

US3882016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:45:55

US3882016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:45:55

US3882016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'May 2020'	System	11 Nov 2020 02:45:55

US3882016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2020'	System	11 Nov 2020 02:45:55

US3882016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:45:55

US3882016

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:45:55

US3882016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User coded data point as SOC: Psychiatric disorders, HLGT: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Suicide attempt, LLT: Attempted suicide - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 05:24:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 05:24:49
Data point term sent to Coder	System	11 Nov 2020 02:47:35
User entered 'H/O: attempted suicide'	Suchi Tiwari (b) (4)	11 Nov 2020 02:46:46

US3882016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '07 May 2020'	Suchi Tiwari (b) (4)	11 Nov 2020 02:46:46

US3882016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:46:46

US3882016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:46:46

US3882016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:46:46

US3882016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:46:46

US3882016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'May 2020'	System	11 Nov 2020 02:46:46

US3882016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2020'	System	11 Nov 2020 02:46:46

US3882016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:46:46

US3882016

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:46:46

US3882016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User coded data point as SOC: Psychiatric disorders, HLGT: Disturbances in thinking and perception, HLT: Delusional symptoms, PT: Delusion, LLT: Delusions - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 06:58:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 06:58:45
Data point term sent to Coder	System	11 Nov 2020 02:47:37
User entered 'Psychotic disorder with delusions caused by stimulant'	Suchi Tiwari (b) (4)	11 Nov 2020 02:47:28

US3882016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '03 Feb 2020'	Suchi Tiwari (b) (4)	11 Nov 2020 02:47:28

US3882016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:47:28

US3882016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:47:28

US3882016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:47:28

US3882016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:47:28

US3882016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'Feb 2020'	System	11 Nov 2020 02:47:28

US3882016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2020'	System	11 Nov 2020 02:47:28

US3882016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:47:28

US3882016

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:47:28

US3882016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User coded data point as SOC: Social circumstances, HLG: Legal issues, HLT: Crime victims, PT: Victim of (b) (6) LLT: Victim of (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 04:49:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 04:49:44
Data point term sent to Coder	System	11 Nov 2020 02:48:37
User entered 'Adult victim of (b) (6)	Suchi Tiwari (b) (4)	11 Nov 2020 02:47:52
(b) (6)	(b) (4)	

US3882016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '15 Jan 2019'	Suchi Tiwari (b) (4)	11 Nov 2020 02:47:52

US3882016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:47:52

US3882016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:47:52

US3882016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:47:52

US3882016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:47:52

US3882016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:29

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'Jan 2019'	System	11 Nov 2020 02:47:52

US3882016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2019'	System	11 Nov 2020 02:47:52

US3882016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:47:52

US3882016

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:47:52

US3882016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:52:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:52:44
Data point term sent to Coder	System	11 Nov 2020 02:51:38
User entered 'Chronic post-traumatic stress disorder'	Suchi Tiwari (b) (4)	11 Nov 2020 02:51:03

US3882016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 00:41:46
User closed query '15Jan2019 is noted as start date on source. Please clarify and make any updates an necessary. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 00:40:11
Query '15Jan2019 is noted as start date on source. Please clarify and make any updates an necessary. ' answered with 'Nov 30 2016 is the correct date. Source has been updated' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 00:23:36
User opened query '15Jan2019 is noted as start date on source. Please clarify and make any updates an necessary. ' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 22:48:05
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 22:46:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '30 Nov 2016'	Suchi Tiwari (b) (4)	11 Nov 2020 02:51:03

US3882016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:51:03

US3882016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:51:03

US3882016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:51:03

US3882016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:51:03

US3882016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'Nov 2016'	System	11 Nov 2020 02:51:03

US3882016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2016'	System	11 Nov 2020 02:51:03

US3882016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:51:03

US3882016

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:51:03

US3882016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcoholism, LLT: Alcohol dependence syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:52:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:52:44
Data point term sent to Coder	System	11 Nov 2020 02:51:38
User entered 'Alcohol dependence'	Suchi Tiwari (b) (4)	11 Nov 2020 02:51:22

US3882016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '15 Aug 2018'	Suchi Tiwari (b) (4)	11 Nov 2020 02:51:22

US3882016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:51:22

US3882016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:51:22

US3882016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:51:22

US3882016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:51:22

US3882016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'Aug 2018'	System	11 Nov 2020 02:51:22

US3882016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2018'	System	11 Nov 2020 02:51:22

US3882016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:51:22

US3882016

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:51:22

US3882016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Drug dependence, LLT: Cocaine dependence - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:56:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:56:56
Data point term sent to Coder	System	11 Nov 2020 02:55:40
User entered 'Cocaine dependence'	Suchi Tiwari (b) (4)	11 Nov 2020 02:54:53

US3882016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '15 Aug 2018'	Suchi Tiwari (b) (4)	11 Nov 2020 02:54:53

US3882016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:54:53

US3882016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:54:53

US3882016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:54:53

US3882016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:54:53

US3882016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'Aug 2018'	System	11 Nov 2020 02:54:53

US3882016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2018'	System	11 Nov 2020 02:54:53

US3882016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:54:53

US3882016

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:54:53

US3882016

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User coded data point as SOC: Psychiatric disorders, HLTG: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Nicotine dependence, LLT: Nicotine dependence - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:56:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:56:55
Data point term sent to Coder	System	11 Nov 2020 02:55:39
User entered 'Nicotine dependence'	Suchi Tiwari (b) (4)	11 Nov 2020 02:55:29

US3882016

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '09 Jul 2018'	Suchi Tiwari (b) (4)	11 Nov 2020 02:55:29

US3882016

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:55:29

US3882016

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:55:29

US3882016

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:55:29

US3882016

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:55:29

US3882016

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'Jul 2018'	System	11 Nov 2020 02:55:29

US3882016

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2018'	System	11 Nov 2020 02:55:29

US3882016

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:55:29

US3882016

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:55:29

US3882016

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:57:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:57:44
Data point term sent to Coder	System	11 Nov 2020 02:56:40
User entered 'MI - Myocardial infarction'	Suchi Tiwari (b) (4) (b) (4)	11 Nov 2020 02:56:21

US3882016

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '02 Mar 2017'	Suchi Tiwari (b) (4)	11 Nov 2020 02:56:21

US3882016

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:56:21

US3882016

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:56:21

US3882016

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:56:21

US3882016

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:56:21

US3882016

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'Mar 2017'	System	11 Nov 2020 02:56:21

US3882016

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2017'	System	11 Nov 2020 02:56:21

US3882016

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:56:21

US3882016

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:56:21

US3882016

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Coxarthrosis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 03:13:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 03:13:43
Data point term sent to Coder	System	11 Nov 2020 02:57:40
User entered 'Arthritis of right hip'	Suchi Tiwari (b) (4)	11 Nov 2020 02:56:45

US3882016

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '16 Feb 2017'	Suchi Tiwari (b) (4)	11 Nov 2020 02:56:45

US3882016

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:56:45

US3882016

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:56:45

US3882016

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:56:45

US3882016

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:56:45

US3882016

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'Feb 2017'	System	11 Nov 2020 02:56:45

US3882016

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2017'	System	11 Nov 2020 02:56:45

US3882016

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:56:45

US3882016

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:56:45

US3882016

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Coxarthrosis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 03:00:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 03:00:47
Data point term sent to Coder	System	11 Nov 2020 02:59:41
User entered 'Arthritis of left hip'	Suchi Tiwari (b) (4)	11 Nov 2020 02:58:59

US3882016

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '16 Feb 2017'	Suchi Tiwari (b) (4)	11 Nov 2020 02:58:59

US3882016

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:58:59

US3882016

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:58:59

US3882016

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:58:59

US3882016

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:58:59

US3882016

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'Feb 2017'	System	11 Nov 2020 02:58:59

US3882016

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2017'	System	11 Nov 2020 02:58:59

US3882016

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:58:59

US3882016

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 02:58:59

US3882016

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Colostomy, LLT: Colostomy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 05:02:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 05:02:46
Data point term sent to Coder	System	11 Nov 2020 03:00:42
User entered 'Colostomy present'	Suchi Tiwari (b) (4)	11 Nov 2020 03:00:08

US3882016

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '20 Nov 2003'	Suchi Tiwari (b) (4)	11 Nov 2020 03:00:08

US3882016

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 03:00:08

US3882016

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User closed query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 15:50:07
Query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'A colostomy is present on the subject and permanent. There is no end date to have it removed.' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	28 Jan 2021 22:33:57
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	28 Jan 2021 22:33:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Vigil (b) (4) (b) (4)	28 Jan 2021 22:33:54
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	28 Jan 2021 22:33:01
Signature has been broken.	Lauren Vigil (b) (4) (b) (4)	28 Jan 2021 22:33:01
User entered 'No (N)' reason for change: Data Entry Error	Lauren Vigil (b) (4) (b) (4)	28 Jan 2021 22:33:01
User opened query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:40:14
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered 'Yes (Y)'	Suchi Tiwari (b) (4) (b) (4)	11 Nov 2020 03:00:08

US3882016

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:29

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 03:00:08

US3882016

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:16:11
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 03:00:08

US3882016

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'Nov 2003'	System	11 Nov 2020 03:00:08

US3882016

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2003'	System	11 Nov 2020 03:00:08

US3882016

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 03:00:08

US3882016

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	11 Nov 2020 03:00:08

US3882016

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	06 Mar 2021 23:05:40
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 22:12:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 22:12:01
Data point term sent to Coder	System	25 Feb 2021 22:11:41
User entered 'INSOMNIA'	Justine Velandria (b) (4)	25 Feb 2021 22:11:00
	(b) (4)	

US3882016

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	06 Mar 2021 23:05:40
User entered empty.	Justine Velandria (b) (4)	25 Feb 2021 22:11:00

US3882016

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	06 Mar 2021 23:05:40
User entered 'I'	Justine Velandria (b) (4)	25 Feb 2021 22:11:00

US3882016

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	06 Mar 2021 23:05:40
User entered 'Yes (Y)'	Justine Velandria (b) (4)	25 Feb 2021 22:11:00

US3882016

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:29

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	06 Mar 2021 23:05:40
User entered empty.	Justine Velandria (b) (4)	25 Feb 2021 22:11:00

US3882016

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:43:24
User signature succeeded.	Michael Lewis (b) (4)	06 Mar 2021 23:05:40
User entered '0'	Justine Velandria (b) (4)	25 Feb 2021 22:11:00

US3882016

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	25 Feb 2021 22:11:00

US3882016

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	25 Feb 2021 22:11:00

US3882016

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	25 Feb 2021 22:11:00

US3882016

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	25 Feb 2021 22:11:00

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:48:19
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:41:42

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:48:19
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '03 Sep 2020'	Suchi Tiwari (b) (4)	05 Sep 2020 20:41:42

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:48:19
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '13:35'	Suchi Tiwari (b) (4)	05 Sep 2020 20:41:42

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '03 Sep 2020 13:35'	System	05 Sep 2020 20:41:42

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:48:19
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '67' in	Suchi Tiwari (b) (4)	05 Sep 2020 20:41:42
DataPoint set to visible.	(b) (4) System	05 Sep 2020 20:37:34

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:48:19
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '168' lb	Suchi Tiwari (b) (4)	05 Sep 2020 20:41:42
DataPoint set to visible.	(b) (4) System	05 Sep 2020 20:37:34

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '26.36754'	System	05 Sep 2020 20:41:42
DataPoint set to visible.	System	05 Sep 2020 20:37:34

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'kg/m2'	System	05 Sep 2020 20:41:42
DataPoint set to visible.	System	05 Sep 2020 20:37:34

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:48:19
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '98.5' F	Suchi Tiwari (b) (4)	05 Sep 2020 20:41:42

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:48:19
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Oral (Oral)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:41:42

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:48:19
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:41:42

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:48:19
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '60'	Suchi Tiwari (b) (4)	05 Sep 2020 20:41:42

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'bpm'	System	05 Sep 2020 20:41:42

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:48:19
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '14'	Suchi Tiwari (b) (4)	05 Sep 2020 20:41:42

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'breaths/min'	System	05 Sep 2020 20:41:42

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:48:19
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '117'	Suchi Tiwari (b) (4)	05 Sep 2020 20:41:42

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'mmHg'	System	05 Sep 2020 20:41:42

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:48:19
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '77'	Suchi Tiwari (b) (4)	05 Sep 2020 20:41:42

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'mmHg'	System	05 Sep 2020 20:41:42

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:04:00

US3882016

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00

US3882016

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:48:32
User signature succeeded.	Michael Lewis (b) (4)	08 Sep 2020 23:10:03
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:42:31

US3882016

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:48:32
User signature succeeded.	Michael Lewis (b) (4)	08 Sep 2020 23:10:03
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 12:17:26
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		05 Sep 2020 20:42:31
User entered '03 Sep 2020'	Suchi Tiwari (b) (4) (b) (4)	05 Sep 2020 20:42:31

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 20:44:45
User entered 'No (N)' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:45
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:14
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 20:44:45
User entered 'No (N)' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:45
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:14
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

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)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 20:44:45
User entered 'No (N)' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:45
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:14
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

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)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 20:44:45
User entered 'No (N)' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:45
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:14
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 20:44:45
User entered 'No (N)' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:45
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:14
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

[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)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 20:44:45
User entered 'No (N)' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:45
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:14
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

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)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 20:44:45
User entered 'No (N)' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:45
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:14
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

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)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 20:44:45
User entered 'No (N)' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:45
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:14
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

[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)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 20:44:45
User entered 'No (N)' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:45
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:14
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

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)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 20:44:45
User entered 'No (N)' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:45
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:14
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

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)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 20:44:45
User entered 'No (N)' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:45
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:44:14
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'unemployed'	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '0'	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '0'	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

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)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '0'	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

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)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'I'	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

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)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '0'	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '0'	Suchi Tiwari (b) (4) (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '0'	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:44:14

US3882016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:17:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:50
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	04 Sep 2020 18:04:39

US3882016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:50
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '04 Sep 2020'	Suchi Tiwari (b) (4)	04 Sep 2020 18:04:39

US3882016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:49:50
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Clinic (Clinic)'	Suchi Tiwari (b) (4)	04 Sep 2020 18:04:39

US3882016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:17:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'VISIT1'	System	04 Sep 2020 18:04:39

US3882016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:29:29
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:09:31

US3882016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:29

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:29:29
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '145209'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:09:31

US3882016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:29

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:29:29
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:09:31

US3882016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:29

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)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:29:29
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'No (N)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:20:17

US3882016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:29

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)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:29:29
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'No (N)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:20:17

US3882016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:29

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:29:29
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'No (N)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:20:17

US3882016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:29

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:29:29
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:27:39
User entered 'No (N)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:20:17

US3882016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:29

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:29:29
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'No (N)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:20:17

US3882016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:29

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:29:29
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
Signature has been broken.	Sara Wong (b) (4)	02 Oct 2020 20:23:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Wong (b) (4)	02 Oct 2020 20:23:42
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 17:51:21
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:19:38
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:19:37

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	11 Nov 2020 00:34:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:03:14
Signature has been broken.	Lauren Vigil (b) (4)	10 Nov 2020 23:01:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 23:01:31
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 05:32:58
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 05:32:53
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '67' in	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02
	(b) (4)	

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	11 Nov 2020 00:34:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:03:16
Signature has been broken.	Lauren Vigil (b) (4)	10 Nov 2020 23:01:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 23:01:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '168' lb	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	11 Nov 2020 00:34:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:03:14
Signature has been broken.	Lauren Vigil (b) (4)	10 Nov 2020 23:01:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 23:01:31
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 05:32:58
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 05:32:53
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '67' in	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	11 Nov 2020 00:34:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:03:16
Signature has been broken.	Lauren Vigil (b) (4)	10 Nov 2020 23:01:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 23:01:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '168' lb	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User accepted default value 'Pre-Dose (PREDOSE)'	Suchi Tiwari (b) (4) (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:36:06
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:36:26
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '04 Sep 2020'	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:36:27
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '11:20'	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '04 Sep 2020 11:20'	System	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:36:29
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '98.8' F	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:36:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Oral (Oral)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:36:48
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:36:57
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:58:48
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Sep 2020 20:58:48
User entered '85' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:48
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:58:02
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'bpm'	System	05 Sep 2020 20:58:48
User entered empty.	System	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:36:59
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:58:48
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Sep 2020 20:58:48
User entered '15' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:48
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:58:02
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'breaths/min'	System	05 Sep 2020 20:58:48
User entered empty.	System	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:37:20
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:58:48
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Sep 2020 20:58:48
User entered '115' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:48
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Sep 2020 20:58:02
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'mmHg'	System	05 Sep 2020 20:58:48
User entered empty.	System	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:37:22
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:58:48
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Sep 2020 20:58:48
User entered '86' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:48
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:58:02
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'mmHg'	System	05 Sep 2020 20:58:48
User entered empty.	System	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	11 Nov 2020 00:34:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:03:14
Signature has been broken.	Lauren Vigil (b) (4)	10 Nov 2020 23:01:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 23:01:31
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 05:32:58
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 05:32:53
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '67' in	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	11 Nov 2020 00:34:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:03:16
Signature has been broken.	Lauren Vigil (b) (4)	10 Nov 2020 23:01:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 23:01:31
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '168' lb	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User accepted default value 'Post-Dose (POSTDOSE)'	Suchi Tiwari (b) (4) (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:35:27
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:35:28
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '04 Sep 2020'	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:21:41
User closed query 'Per CDM: The treatment time on the Exposure CRF is 12:07 and the Vital Signs Post Dose Time of Assessment is 12:30 which has 23 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	19 Nov 2020 07:32:33
	Michael Lewis (b) (4)	11 Nov 2020 00:34:16
Query 'Per CDM: The treatment time on the Exposure CRF is 12:07 and the Vital Signs Post Dose Time of Assessment is 12:30 which has 23 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed' answered with 'updated' (Site from DM). Signature has been broken.	Lauren Vigil (b) (4)	16 Oct 2020 22:01:17
	(b) (4)	
	Lauren Vigil (b) (4)	16 Oct 2020 22:01:08
User entered '12:40' reason for change: Data Entry Error	(b) (4)	
	Lauren Vigil (b) (4)	16 Oct 2020 22:01:08
User opened query 'Per CDM: The treatment time on the Exposure CRF is 12:07 and the Vital Signs Post Dose Time of Assessment is 12:30 which has 23 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	12 Oct 2020 14:18:40
	(b) (4), (b) (6)	
	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '12:30'	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02
	(b) (4)	

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '04 Sep 2020 12:40'	System	16 Oct 2020 22:01:08
User entered '04 Sep 2020 12:30'	System	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:35:00
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '97.6' F	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:35:32
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Oral (Oral)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:35:40
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:35:04
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:59:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Sep 2020 20:59:20
User entered '66' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:59:20
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:58:02
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'bpm'	System	05 Sep 2020 20:59:20
User entered empty.	System	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:35:05
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:59:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Sep 2020 20:59:20
User entered '15' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:59:20
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:58:02
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'breaths/min'	System	05 Sep 2020 20:59:20
User entered empty.	System	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:35:07
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:59:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Sep 2020 20:59:20
User entered '115' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:59:20
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:58:02
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'mmHg'	System	05 Sep 2020 20:59:20
User entered empty.	System	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:35:14
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:59:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Sep 2020 20:59:20
User entered '78' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 20:59:20
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:58:02
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'mmHg'	System	05 Sep 2020 20:59:20
User entered empty.	System	05 Sep 2020 20:58:02

US3882016

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:56:03
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	05 Sep 2020 20:55:31

US3882016

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:56:03
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '04 Sep 2020'	Suchi Tiwari (b) (4)	05 Sep 2020 20:55:31

US3882016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:38:03
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	05 Sep 2020 21:00:53

US3882016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:38:03
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 21:00:53

US3882016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

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)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:38:03
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 21:00:53

US3882016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'MRNA-1273 OR PLACEBO'	System	05 Sep 2020 21:00:53

US3882016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:38:03
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '04 Sep 2020'	Suchi Tiwari (b) (4)	05 Sep 2020 21:00:53

US3882016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:38:03
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '12:07'	Suchi Tiwari (b) (4) (b) (4)	05 Sep 2020 21:00:53

US3882016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '04 Sep 2020 12:07'	System	05 Sep 2020 21:00:53

US3882016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:38:03
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Left Arm (LEFT ARM)'	Suchi Tiwari (b) (4)	05 Sep 2020 21:00:53

US3882016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:38:03
User entered 'ONCE'	System	05 Sep 2020 21:00:53

US3882016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'INTRAMUSCULAR'	System	05 Sep 2020 21:00:53

US3882016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:38:36
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	05 Sep 2020 21:01:11

US3882016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:38:44
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '04 Sep 2020'	Suchi Tiwari (b) (4)	05 Sep 2020 21:01:11

US3882016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	14 Nov 2020 00:24:30
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:42:22
User closed query 'Source document notes assessment time was 11:40. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 22:42:20
Query 'Source document notes assessment time was 11:40. Please reconcile. ' answered with 'updated' (Site from CRA).	Lauren Vigil (b) (4)	12 Nov 2020 22:07:35
Signature has been broken.	Lauren Vigil (b) (4)	12 Nov 2020 22:07:29
User entered '11:40' reason for change: Data Entry Error	Lauren Vigil (b) (4)	12 Nov 2020 22:07:29
User opened query 'Source document notes assessment time was 11:40. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 06:41:33
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '11:45'	Suchi Tiwari (b) (4)	05 Sep 2020 21:01:11

US3882016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '04 Sep 2020 11:40'	System	12 Nov 2020 22:07:29
User entered '04 Sep 2020 11:45'	System	05 Sep 2020 21:01:11

US3882016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:17:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:39:00
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '04 Sep 2020'	Suchi Tiwari (b) (4)	05 Sep 2020 21:04:04

US3882016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:17:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Suchi Tiwari (b) (4) (b) (4)	05 Sep 2020 21:04:04

US3882016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:17:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:39:00
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	05 Sep 2020 21:04:04

US3882016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:17:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:39:00
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered '11:45'	Suchi Tiwari (b) (4)	05 Sep 2020 21:04:04

US3882016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:17:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '04 Sep 2020 11:45'	System	05 Sep 2020 21:04:04

US3882016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:17:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Suchi Tiwari (b) (4) (b) (4)	05 Sep 2020 21:04:04

US3882016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:17:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:39:00
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 21:04:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 21:04:10
User entered 'No (N)' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	05 Sep 2020 21:04:10
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 21:04:04
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 21:04:04

US3882016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:17:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:39:00
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered empty.	Suchi Tiwari (b) (4)	05 Sep 2020 21:04:04

US3882016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:17:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	05 Sep 2020 21:04:04

US3882016

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:41:51
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:57:00
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	05 Sep 2020 21:04:18

US3882016

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'I'	System	05 Sep 2020 21:04:18

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '04 Sep 2020 12:27'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '04 Sep 2020 14:57'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '04 Sep 2020 15:52'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '05 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 2'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-05T15:57:26', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '2d95b27b-f048-4505-945d-189ed59d22fe' User entered 'Yes (Y)'	System	05 Sep 2020 22:58:06
	System	05 Sep 2020 22:58:06

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-05T15:57:49', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '2d95b27b-f048-4505-945d-189ed59d22fe' User entered '98.4'	System	05 Sep 2020 22:58:06
	System	05 Sep 2020 22:58:06

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-05T15:57:54', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '2d95b27b-f048-4505-945d-189ed59d22fe' User entered 'No (N)'	System	05 Sep 2020 22:58:06
	System	05 Sep 2020 22:58:06

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-05T15:58:01', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '2d95b27b-f048-4505-945d-189ed59d22fe' User entered '05 Sep 2020 15:58'	System	05 Sep 2020 22:58:06
	System	05 Sep 2020 22:58:06

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '05 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 3'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-06T16:02:46', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '3a3e3d52-d3f7-4643-a186-d9a867ae1191' User entered 'Yes (Y)'	System	06 Sep 2020 23:03:07
	System	06 Sep 2020 23:03:07

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-06T16:02:53', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '3a3e3d52-d3f7-4643-a186-d9a867ae1191' User entered '98.8'	System	06 Sep 2020 23:03:07
	System	06 Sep 2020 23:03:07

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-06T16:02:58', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '3a3e3d52-d3f7-4643-a186-d9a867ae1191'	System	06 Sep 2020 23:03:07
User entered 'No (N)'	System	06 Sep 2020 23:03:07

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-06T16:03:02', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '3a3e3d52-d3f7-4643-a186-d9a867ae1191' User entered '06 Sep 2020 16:03'	System	06 Sep 2020 23:03:07
	System	06 Sep 2020 23:03:07

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 4'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-07T15:51:34', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '6999f4ad-d70e-4ab9-ac18-da71b9b4692a' User entered 'Yes (Y)'	System	07 Sep 2020 22:52:11
	System	07 Sep 2020 22:52:11

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-07T15:51:42', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '6999f4ad-d70e-4ab9-ac18-da71b9b4692a' User entered '98.7'	System	07 Sep 2020 22:52:11
	System	07 Sep 2020 22:52:11

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-07T15:52:04', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '6999f4ad-d70e-4ab9-ac18-da71b9b4692a' User entered 'No (N)'	System	07 Sep 2020 22:52:11
	System	07 Sep 2020 22:52:11

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-07T15:52:07', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '6999f4ad-d70e-4ab9-ac18-da71b9b4692a' User entered '07 Sep 2020 15:52'	System	07 Sep 2020 22:52:11
	System	07 Sep 2020 22:52:11

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 5'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-08T15:56:02', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '3764a05c-0d54-490c-9840-e9bb8f34f4da' User entered 'Yes (Y)'	System	08 Sep 2020 22:56:25
	System	08 Sep 2020 22:56:25

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-08T15:56:14', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '3764a05c-0d54-490c-9840-e9bb8f34f4da' User entered '98.4'	System	08 Sep 2020 22:56:25
	System	08 Sep 2020 22:56:25

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-08T15:56:21', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '3764a05c-0d54-490c-9840-e9bb8f34f4da'	System	08 Sep 2020 22:56:25
User entered 'No (N)'	System	08 Sep 2020 22:56:25

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-08T15:56:23', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '3764a05c-0d54-490c-9840-e9bb8f34f4da'	System	08 Sep 2020 22:56:25
User entered '08 Sep 2020 15:56'	System	08 Sep 2020 22:56:25

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 6'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-09T15:52:49', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '9079d98e-c106-49c4-993b-52f77e28023a' User entered 'Yes (Y)'	System	09 Sep 2020 22:54:01
	System	09 Sep 2020 22:54:01

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-09T15:53:55', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '9079d98e-c106-49c4-993b-52f77e28023a' User entered '98.6'	System	09 Sep 2020 22:54:01
	System	09 Sep 2020 22:54:01

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-09T15:53:42', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '9079d98e-c106-49c4-993b-52f77e28023a' User entered 'No (N)'	System	09 Sep 2020 22:54:01
	System	09 Sep 2020 22:54:01

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-09T15:53:58', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '9079d98e-c106-49c4-993b-52f77e28023a' User entered '09 Sep 2020 15:53'	System	09 Sep 2020 22:54:01
	System	09 Sep 2020 22:54:01

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 7'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-10T15:46:18', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '433f34f5-7943-43fa-bf3b-308873ffc692'	System	10 Sep 2020 22:47:12
User entered 'Yes (Y)'	System	10 Sep 2020 22:47:12

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-10T15:47:00', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '433f34f5-7943-43fa-bf3b-308873ffc692'	System	10 Sep 2020 22:47:12
User entered '98.4'	System	10 Sep 2020 22:47:12

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-10T15:47:05', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '433f34f5-7943-43fa-bf3b-308873ffc692'	System	10 Sep 2020 22:47:12
User entered 'No (N)'	System	10 Sep 2020 22:47:12

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-10T15:47:08', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '433f34f5-7943-43fa-bf3b-308873ffc692'	System	10 Sep 2020 22:47:12
User entered '10 Sep 2020 15:47'	System	10 Sep 2020 22:47:12

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '04 Sep 2020 12:27'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '04 Sep 2020 14:57'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '04 Sep 2020 15:52'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '05 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 2'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-05T15:57:07', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'afc226d0-d999-49ed-8b1d-593eb4fbe43f' User entered 'None (1)'	System	05 Sep 2020 22:57:23
	System	05 Sep 2020 22:57:23

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-05T15:56:22', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'afc226d0-d999-49ed-8b1d-593eb4fbe43f' User entered 'No (N)'	System	05 Sep 2020 22:57:23
	System	05 Sep 2020 22:57:23

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-05T15:56:29', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'afc226d0-d999-49ed-8b1d-593eb4fbe43f' User entered 'No (N)'	System	05 Sep 2020 22:57:23
	System	05 Sep 2020 22:57:23

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-05T15:56:46', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'afc226d0-d999-49ed-8b1d-593eb4fbe43f' User entered 'None (1)'	System	05 Sep 2020 22:57:23
	System	05 Sep 2020 22:57:23

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-05T15:57:14', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'afc226d0-d999-49ed-8b1d-593eb4fbe43f' User entered '05 Sep 2020 15:57'	System	05 Sep 2020 22:57:23
	System	05 Sep 2020 22:57:23

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '05 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 3'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-06T16:01:34', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '324cd5bf-904a-4299-bc7a-f3801c58f766'	System	06 Sep 2020 23:01:57
User entered 'None (1)'	System	06 Sep 2020 23:01:57

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-06T16:01:37', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '324cd5bf-904a-4299-bc7a-f3801c58f766'	System	06 Sep 2020 23:01:57
User entered 'No (N)'	System	06 Sep 2020 23:01:57

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-06T16:01:42', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '324cd5bf-904a-4299-bc7a-f3801c58f766'	System	06 Sep 2020 23:01:57
User entered 'No (N)'	System	06 Sep 2020 23:01:57

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-06T16:01:50', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '324cd5bf-904a-4299-bc7a-f3801c58f766'	System	06 Sep 2020 23:01:57
User entered 'None (1)'	System	06 Sep 2020 23:01:57

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-06T16:01:54', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '324cd5bf-904a-4299-bc7a-f3801c58f766'	System	06 Sep 2020 23:01:57
User entered '06 Sep 2020 16:01'	System	06 Sep 2020 23:01:57

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 4'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-07T15:50:09', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '4ad15c3a-3cc0-4ca9-a44c-f15e844080e2'	System	07 Sep 2020 22:51:28
User entered 'None (1)'	System	07 Sep 2020 22:51:28

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-07T15:51:17', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '4ad15c3a-3cc0-4ca9-a44c-f15e844080e2' User entered 'No (N)'	System	07 Sep 2020 22:51:28
	System	07 Sep 2020 22:51:28

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-07T15:51:20', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '4ad15c3a-3cc0-4ca9-a44c-f15e844080e2'	System	07 Sep 2020 22:51:28
User entered 'No (N)'	System	07 Sep 2020 22:51:28

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-07T15:51:23', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '4ad15c3a-3cc0-4ca9-a44c-f15e844080e2'	System	07 Sep 2020 22:51:28
User entered 'None (1)'	System	07 Sep 2020 22:51:28

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-07T15:51:26', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '4ad15c3a-3cc0-4ca9-a44c-f15e844080e2' User entered '07 Sep 2020 15:51'	System	07 Sep 2020 22:51:28
	System	07 Sep 2020 22:51:28

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 5'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-08T15:55:38', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '662f21f5-617e-4f46-b9f7-c22dbe27f18b'	System	08 Sep 2020 22:55:52
User entered 'None (1)'	System	08 Sep 2020 22:55:52

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-08T15:55:40', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '662f21f5-617e-4f46-b9f7-c22dbe27f18b' User entered 'No (N)'	System	08 Sep 2020 22:55:52
	System	08 Sep 2020 22:55:52

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-08T15:55:42', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '662f21f5-617e-4f46-b9f7-c22dbe27f18b' User entered 'No (N)'	System	08 Sep 2020 22:55:52
	System	08 Sep 2020 22:55:52

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-08T15:55:44', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '662f21f5-617e-4f46-b9f7-c22dbe27f18b' User entered 'None (1)'	System	08 Sep 2020 22:55:52
	System	08 Sep 2020 22:55:52

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-08T15:55:50', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '662f21f5-617e-4f46-b9f7-c22dbe27f18b' User entered '08 Sep 2020 15:55'	System	08 Sep 2020 22:55:52
	System	08 Sep 2020 22:55:52

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 6'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-09T15:52:28', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '543649b0-da90-4ed3-b0b4-5dbfc3824aef' User entered 'None (1)'	System	09 Sep 2020 22:52:42
	System	09 Sep 2020 22:52:42

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-09T15:52:31', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '543649b0-da90-4ed3-b0b4-5dbfc3824aef' User entered 'No (N)'	System	09 Sep 2020 22:52:42
	System	09 Sep 2020 22:52:42

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-09T15:52:33', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '543649b0-da90-4ed3-b0b4-5dbfc3824aef' User entered 'No (N)'	System	09 Sep 2020 22:52:42
	System	09 Sep 2020 22:52:42

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-09T15:52:35', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '543649b0-da90-4ed3-b0b4-5dbfc3824aef' User entered 'None (1)'	System	09 Sep 2020 22:52:42
	System	09 Sep 2020 22:52:42

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-09T15:52:39', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '543649b0-da90-4ed3-b0b4-5dbfc3824aef' User entered '09 Sep 2020 15:52'	System	09 Sep 2020 22:52:42
	System	09 Sep 2020 22:52:42

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 7'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-10T15:46:00', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '488e02aa-eb87-47da-929b-6ed6ffa24baa'	System	10 Sep 2020 22:46:13
User entered 'None (1)'	System	10 Sep 2020 22:46:13

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-10T15:46:03', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '488e02aa-eb87-47da-929b-6ed6ffa24baa'	System	10 Sep 2020 22:46:13
User entered 'No (N)'	System	10 Sep 2020 22:46:13

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-10T15:46:06', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '488e02aa-eb87-47da-929b-6ed6ffa24baa'	System	10 Sep 2020 22:46:13
User entered 'No (N)'	System	10 Sep 2020 22:46:13

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-10T15:46:08', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '488e02aa-eb87-47da-929b-6ed6ffa24baa'	System	10 Sep 2020 22:46:13
User entered 'None (1)'	System	10 Sep 2020 22:46:13

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-10T15:46:11', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '488e02aa-eb87-47da-929b-6ed6ffa24baa'	System	10 Sep 2020 22:46:13
User entered '10 Sep 2020 15:46'	System	10 Sep 2020 22:46:13

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '04 Sep 2020 12:27'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '04 Sep 2020 14:57'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '04 Sep 2020 15:52'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '05 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 2'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-05T15:58:13', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'f790bd3a-3ce2-4087-a392-2b77a39cc69b' User entered 'None (0)'	System	05 Sep 2020 22:58:47
	System	05 Sep 2020 22:58:47

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-05T15:58:17', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'f790bd3a-3ce2-4087-a392-2b77a39cc69b' User entered 'None (0)'	System	05 Sep 2020 22:58:47
	System	05 Sep 2020 22:58:47

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-05T15:58:22', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'f790bd3a-3ce2-4087-a392-2b77a39cc69b' User entered 'None (0)'	System	05 Sep 2020 22:58:47
	System	05 Sep 2020 22:58:47

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-05T15:58:26', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'f790bd3a-3ce2-4087-a392-2b77a39cc69b' User entered 'None (0)'	System	05 Sep 2020 22:58:47
	System	05 Sep 2020 22:58:47

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-05T15:58:31', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'f790bd3a-3ce2-4087-a392-2b77a39cc69b' User entered 'None (0)'	System	05 Sep 2020 22:58:47
	System	05 Sep 2020 22:58:47

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-05T15:58:35', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'f790bd3a-3ce2-4087-a392-2b77a39cc69b' User entered 'None (0)'	System	05 Sep 2020 22:58:47
	System	05 Sep 2020 22:58:47

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-05T15:58:43', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'f790bd3a-3ce2-4087-a392-2b77a39cc69b' User entered 'No (N)'	System	05 Sep 2020 22:58:47
	System	05 Sep 2020 22:58:47

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-05T15:58:46', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'f790bd3a-3ce2-4087-a392-2b77a39cc69b' User entered '05 Sep 2020 15:58'	System	05 Sep 2020 22:58:47
	System	05 Sep 2020 22:58:47

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '05 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 3'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-06T16:02:00', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '2dce3eb5-8d65-40d9-8c55-ca6f8426747b' User entered 'None (0)'	System	06 Sep 2020 23:02:39
	System	06 Sep 2020 23:02:39

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-06T16:02:03', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '2dce3eb5-8d65-40d9-8c55-ca6f8426747b' User entered 'None (0)'	System	06 Sep 2020 23:02:39
	System	06 Sep 2020 23:02:39

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-06T16:02:18', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '2dce3eb5-8d65-40d9-8c55-ca6f8426747b' User entered 'None (0)'	System	06 Sep 2020 23:02:39
	System	06 Sep 2020 23:02:39

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-06T16:02:21', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '2dce3eb5-8d65-40d9-8c55-ca6f8426747b' User entered 'None (0)'	System	06 Sep 2020 23:02:39
	System	06 Sep 2020 23:02:39

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-06T16:02:23', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '2dce3eb5-8d65-40d9-8c55-ca6f8426747b' User entered 'None (0)'	System	06 Sep 2020 23:02:39
	System	06 Sep 2020 23:02:39

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-06T16:02:26', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '2dce3eb5-8d65-40d9-8c55-ca6f8426747b' User entered 'None (0)'	System	06 Sep 2020 23:02:39
	System	06 Sep 2020 23:02:39

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-06T16:02:32', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '2dce3eb5-8d65-40d9-8c55-ca6f8426747b'	System	06 Sep 2020 23:02:39
User entered 'Yes (Y)'	System	06 Sep 2020 23:02:39

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-06T16:02:36', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '2dce3eb5-8d65-40d9-8c55-ca6f8426747b' User entered '06 Sep 2020 16:02'	System	06 Sep 2020 23:02:39
	System	06 Sep 2020 23:02:39

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 4'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-07T15:49:36', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '03d42390-bbcb-4db9-8e8a-e84afde4dca6' User entered 'None (0)'	System	07 Sep 2020 22:50:04
	System	07 Sep 2020 22:50:04

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-07T15:49:40', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '03d42390-bbcb-4db9-8e8a-e84afde4dca6' User entered 'None (0)'	System	07 Sep 2020 22:50:04
	System	07 Sep 2020 22:50:04

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-07T15:49:44', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '03d42390-bbcb-4db9-8e8a-e84afde4dca6' User entered 'None (0)'	System	07 Sep 2020 22:50:04
	System	07 Sep 2020 22:50:04

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-07T15:49:48', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '03d42390-bbcb-4db9-8e8a-e84afde4dca6' User entered 'None (0)'	System	07 Sep 2020 22:50:04
	System	07 Sep 2020 22:50:04

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-07T15:49:51', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '03d42390-bbcb-4db9-8e8a-e84afde4dca6' User entered 'None (0)'	System	07 Sep 2020 22:50:04
	System	07 Sep 2020 22:50:04

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-07T15:49:54', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '03d42390-bbcb-4db9-8e8a-e84afde4dca6' User entered 'None (0)'	System	07 Sep 2020 22:50:04
	System	07 Sep 2020 22:50:04

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-07T15:49:58', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '03d42390-bbcb-4db9-8e8a-e84afde4dca6' User entered 'No (N)'	System	07 Sep 2020 22:50:04
	System	07 Sep 2020 22:50:04

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-07T15:50:03', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '03d42390-bbcb-4db9-8e8a-e84afde4dca6'	System	07 Sep 2020 22:50:04
User entered '07 Sep 2020 15:50'	System	07 Sep 2020 22:50:04

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 5'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-08T15:55:19', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'e13e0693-9514-4186-b2d0-f1aa9907a262' User entered 'None (0)'	System	08 Sep 2020 22:55:35
	System	08 Sep 2020 22:55:35

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-08T15:55:21', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'e13e0693-9514-4186-b2d0-f1aa9907a262' User entered 'None (0)'	System	08 Sep 2020 22:55:35
	System	08 Sep 2020 22:55:35

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-08T15:55:23', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'e13e0693-9514-4186-b2d0-f1aa9907a262' User entered 'None (0)'	System	08 Sep 2020 22:55:35
	System	08 Sep 2020 22:55:35

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-08T15:55:25', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'e13e0693-9514-4186-b2d0-f1aa9907a262' User entered 'None (0)'	System	08 Sep 2020 22:55:35
	System	08 Sep 2020 22:55:35

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-08T15:55:26', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'e13e0693-9514-4186-b2d0-f1aa9907a262' User entered 'None (0)'	System	08 Sep 2020 22:55:35
	System	08 Sep 2020 22:55:35

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-08T15:55:28', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'e13e0693-9514-4186-b2d0-f1aa9907a262' User entered 'None (0)'	System	08 Sep 2020 22:55:35
	System	08 Sep 2020 22:55:35

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-08T15:55:31', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'e13e0693-9514-4186-b2d0-f1aa9907a262'	System	08 Sep 2020 22:55:35
User entered 'No (N)'	System	08 Sep 2020 22:55:35

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-08T15:55:33', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'e13e0693-9514-4186-b2d0-f1aa9907a262' User entered '08 Sep 2020 15:55'	System	08 Sep 2020 22:55:35
	System	08 Sep 2020 22:55:35

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 6'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-09T15:52:00', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '211d3d38-d5bc-498f-b8f6-632a32a8c193' User entered 'None (0)'	System	09 Sep 2020 22:52:25
	System	09 Sep 2020 22:52:25

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-09T15:52:03', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '211d3d38-d5bc-498f-b8f6-632a32a8c193' User entered 'None (0)'	System	09 Sep 2020 22:52:25
	System	09 Sep 2020 22:52:25

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-09T15:52:06', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '211d3d38-d5bc-498f-b8f6-632a32a8c193' User entered 'None (0)'	System	09 Sep 2020 22:52:25
	System	09 Sep 2020 22:52:25

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-09T15:52:08', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '211d3d38-d5bc-498f-b8f6-632a32a8c193' User entered 'None (0)'	System	09 Sep 2020 22:52:25
	System	09 Sep 2020 22:52:25

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-09T15:52:10', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '211d3d38-d5bc-498f-b8f6-632a32a8c193' User entered 'None (0)'	System	09 Sep 2020 22:52:25
	System	09 Sep 2020 22:52:25

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-09T15:52:13', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '211d3d38-d5bc-498f-b8f6-632a32a8c193' User entered 'None (0)'	System	09 Sep 2020 22:52:25
	System	09 Sep 2020 22:52:25

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-09T15:52:20', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '211d3d38-d5bc-498f-b8f6-632a32a8c193'	System	09 Sep 2020 22:52:25
User entered 'No (N)'	System	09 Sep 2020 22:52:25

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-09T15:52:23', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '211d3d38-d5bc-498f-b8f6-632a32a8c193' User entered '09 Sep 2020 15:52'	System	09 Sep 2020 22:52:25
	System	09 Sep 2020 22:52:25

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 7'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-10T15:45:35', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '77312ab1-1c86-4b49-bed1-aa23cb86a79a' User entered 'None (0)'	System	10 Sep 2020 22:45:58
	System	10 Sep 2020 22:45:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-10T15:45:38', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '77312ab1-1c86-4b49-bed1-aa23cb86a79a' User entered 'None (0)'	System	10 Sep 2020 22:45:58
	System	10 Sep 2020 22:45:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-10T15:45:40', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '77312ab1-1c86-4b49-bed1-aa23cb86a79a' User entered 'None (0)'	System	10 Sep 2020 22:45:58
	System	10 Sep 2020 22:45:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-10T15:45:42', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '77312ab1-1c86-4b49-bed1-aa23cb86a79a' User entered 'None (0)'	System	10 Sep 2020 22:45:58
	System	10 Sep 2020 22:45:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-10T15:45:44', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '77312ab1-1c86-4b49-bed1-aa23cb86a79a' User entered 'None (0)'	System	10 Sep 2020 22:45:58
	System	10 Sep 2020 22:45:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-10T15:45:46', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '77312ab1-1c86-4b49-bed1-aa23cb86a79a' User entered 'None (0)'	System	10 Sep 2020 22:45:58
	System	10 Sep 2020 22:45:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-10T15:45:54', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '77312ab1-1c86-4b49-bed1-aa23cb86a79a' User entered 'No (N)'	System	10 Sep 2020 22:45:58
	System	10 Sep 2020 22:45:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0F1E00A-9E8D-49B4-AC4D-493C600191D2)', Time: '2020-09-10T15:45:56', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '77312ab1-1c86-4b49-bed1-aa23cb86a79a' User entered '10 Sep 2020 15:45'	System	10 Sep 2020 22:45:58
	System	10 Sep 2020 22:45:58

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 21:00:53

US3882016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 02:03:44
User signature succeeded.	Michael Lewis (b) (4)	12 Sep 2020 16:04:08
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	11 Sep 2020 20:00:07

US3882016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 02:03:44
User signature succeeded.	Michael Lewis (b) (4)	12 Sep 2020 16:04:08
User entered '11 Sep 2020'	Lauren Vigil (b) (4)	11 Sep 2020 20:00:07
	(b) (4)	

US3882016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 02:03:44
User signature succeeded.	Michael Lewis (b) (4)	12 Sep 2020 16:04:08
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	11 Sep 2020 20:00:07

US3882016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 02:03:44
User signature succeeded.	Michael Lewis (b) (4)	12 Sep 2020 16:04:08
User entered empty.	Lauren Vigil (b) (4)	11 Sep 2020 20:00:07
	(b) (4)	

US3882016

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 02:03:50
User signature succeeded.	Michael Lewis (b) (4)	12 Sep 2020 16:04:08
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	11 Sep 2020 20:00:12

US3882016

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'I'	System	11 Sep 2020 20:00:12

US3882016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 02:04:38
User signature succeeded.	Michael Lewis (b) (4)	19 Sep 2020 00:33:51
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	18 Sep 2020 20:42:23

US3882016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 02:04:38
User signature succeeded.	Michael Lewis (b) (4)	19 Sep 2020 00:33:51
User entered '18 Sep 2020'	Lauren Vigil (b) (4)	18 Sep 2020 20:42:23
	(b) (4)	

US3882016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 02:04:38
User signature succeeded.	Michael Lewis (b) (4)	19 Sep 2020 00:33:51
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	18 Sep 2020 20:42:23

US3882016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 02:04:38
User signature succeeded.	Michael Lewis (b) (4)	19 Sep 2020 00:33:51
User entered empty.	Lauren Vigil (b) (4)	18 Sep 2020 20:42:23

US3882016

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 02:04:44
User signature succeeded.	Michael Lewis (b) (4)	19 Sep 2020 00:33:51
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	18 Sep 2020 20:42:29

US3882016

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'I'	System	18 Sep 2020 20:42:29

US3882016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 02:10:56
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	25 Sep 2020 20:11:31

US3882016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 02:10:56
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered '25 Sep 2020'	Lauren Vigil (b) (4)	25 Sep 2020 20:11:31
	(b) (4)	

US3882016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 02:10:56
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	25 Sep 2020 20:11:31

US3882016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 02:10:56
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	25 Sep 2020 20:11:31

US3882016

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 02:11:01
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	25 Sep 2020 20:11:36

US3882016

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'I'	System	25 Sep 2020 20:11:36

US3882016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:43:21
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered 'Yes (Y)'	Sara Wong (b) (4)	02 Oct 2020 20:17:19

US3882016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:43:21
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered '2 Oct 2020'	Sara Wong (b) (4)	02 Oct 2020 20:17:19

US3882016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:43:21
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered 'Clinic (Clinic)'	Sara Wong (b) (4)	02 Oct 2020 20:17:19

US3882016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'VISIT2'	System	02 Oct 2020 20:17:19

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User accepted default value 'Pre-Dose (PREDOSE)'	Sara Wong (b) (4) (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered 'Yes (Y)'	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered '2 Oct 2020'	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered '12:08'	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2 Oct 2020 12:08'	System	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered '97.6' F	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered 'Oral (Oral)'	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered '88'	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'bpm'	System	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered '17'	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'breaths/min'	System	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered '124'	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'mmHg'	System	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered '89'	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'mmHg'	System	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User accepted default value 'Post-Dose (POSTDOSE)'	Sara Wong (b) (4) (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered 'Yes (Y)'	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered '2 Oct 2020'	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered '13:33'	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2 Oct 2020 13:33'	System	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 23:22:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Oct 2020 23:22:30
User entered '98.3' F reason for change: New Information	Sara Wong (b) (4)	02 Oct 2020 23:22:30
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:18:12
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered 'Oral (Oral)'	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 23:22:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Oct 2020 23:22:30
User entered '71' reason for change: New Information	Sara Wong (b) (4)	02 Oct 2020 23:22:30
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:18:12
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'bpm'	System	02 Oct 2020 23:22:30
User entered empty.	System	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 23:22:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Oct 2020 23:22:30
User entered '16' reason for change: New Information	Sara Wong (b) (4)	02 Oct 2020 23:22:30
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:18:12
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'breaths/min'	System	02 Oct 2020 23:22:30
User entered empty.	System	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 23:22:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Oct 2020 23:22:30
User entered '137' reason for change: New Information	Sara Wong (b) (4)	02 Oct 2020 23:22:30
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:18:12
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'mmHg'	System	02 Oct 2020 23:22:30
User entered empty.	System	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 23:22:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Oct 2020 23:22:30
User entered '90' reason for change: New Information	Sara Wong (b) (4)	02 Oct 2020 23:22:30
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 20:18:12
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'mmHg'	System	02 Oct 2020 23:22:30
User entered empty.	System	02 Oct 2020 20:18:12

US3882016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:14
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered 'Yes (Y)'	Sara Wong (b) (4)	02 Oct 2020 20:18:22

US3882016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:14
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered '2 Oct 2020'	Sara Wong (b) (4)	02 Oct 2020 20:18:22

US3882016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:38
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered 'Yes (Y)'	Sara Wong (b) (4)	02 Oct 2020 20:19:21

US3882016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:38
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 20:19:21

US3882016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

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)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:38
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 20:19:21

US3882016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 20:19:21

US3882016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:38
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered '2 Oct 2020'	Sara Wong (b) (4)	02 Oct 2020 20:19:21

US3882016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:38
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered '13:03'	Sara Wong (b) (4)	02 Oct 2020 20:19:21

US3882016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2 Oct 2020 13:03'	System	02 Oct 2020 20:19:21

US3882016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:38
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered 'Left Arm (LEFT ARM)'	Sara Wong (b) (4)	02 Oct 2020 20:19:21

US3882016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:38
User entered 'ONCE'	System	02 Oct 2020 20:19:21

US3882016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 20:19:21

US3882016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:50
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered 'Yes (Y)'	Sara Wong (b) (4)	02 Oct 2020 20:19:35

US3882016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:50
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered '2 Oct 2020'	Sara Wong (b) (4)	02 Oct 2020 20:19:35

US3882016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:46:50
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered '12:50'	Sara Wong (b) (4)	02 Oct 2020 20:19:35

US3882016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2 Oct 2020 12:50'	System	02 Oct 2020 20:19:35

US3882016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:17:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:47:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered '2 Oct 2020'	Sara Wong (b) (4)	02 Oct 2020 20:21:02

US3882016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:17:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sara Wong (b) (4) (b) (4)	02 Oct 2020 20:21:02

US3882016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:17:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:47:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered 'Yes (Y)'	Sara Wong (b) (4)	02 Oct 2020 20:21:02

US3882016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:17:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:47:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered '12:10'	Sara Wong (b) (4)	02 Oct 2020 20:21:02

US3882016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:17:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '2 Oct 2020 12:10'	System	02 Oct 2020 20:21:02

US3882016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:17:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sara Wong (b) (4) (b) (4)	02 Oct 2020 20:21:02

US3882016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:17:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:47:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered 'No (N)'	Sara Wong (b) (4)	02 Oct 2020 20:21:02

US3882016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:17:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:47:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 20:21:02

US3882016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:17:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	02 Oct 2020 20:21:02

US3882016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:47:18
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:03:45
User entered 'Yes (Y)'	Sara Wong (b) (4)	02 Oct 2020 20:17:00

US3882016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	02 Oct 2020 20:17:00

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-02T13:38:10', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'bf9cbfcd-0e5c-47ca-bc8c-fb2caf472f47'	System	02 Oct 2020 20:38:36
User entered 'Yes (Y)'	System	02 Oct 2020 20:38:36

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-02T13:38:18', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'bf9cbfcd-0e5c-47ca-bc8c-fb2caf472f47'	System	02 Oct 2020 20:38:36
User entered '98.3'	System	02 Oct 2020 20:38:36

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-02T13:38:26', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'bf9cbfcd-0e5c-47ca-bc8c-fb2caf472f47'	System	02 Oct 2020 20:38:36
User entered 'No (N)'	System	02 Oct 2020 20:38:36

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-02T13:38:29', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'bf9cbfcd-0e5c-47ca-bc8c-fb2caf472f47'	System	02 Oct 2020 20:38:36
User entered '02 Oct 2020 13:38'	System	02 Oct 2020 20:38:36

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '02 Oct 2020 13:23'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '02 Oct 2020 15:53'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:55:51', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '01030a25-9e2c-41e1-b3f5-62ba7c077ea8'	System	03 Oct 2020 17:56:11
User entered 'Yes (Y)'	System	03 Oct 2020 17:56:11

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:55:56', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '01030a25-9e2c-41e1-b3f5-62ba7c077ea8'	System	03 Oct 2020 17:56:11
User entered '98.7'	System	03 Oct 2020 17:56:11

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:56:02', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '01030a25-9e2c-41e1-b3f5-62ba7c077ea8'	System	03 Oct 2020 17:56:11
User entered 'No (N)'	System	03 Oct 2020 17:56:11

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:56:09', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '01030a25-9e2c-41e1-b3f5-62ba7c077ea8'	System	03 Oct 2020 17:56:11
User entered '03 Oct 2020 10:56'	System	03 Oct 2020 17:56:11

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '02 Oct 2020 16:48'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 2'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T12:01:02', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '53962199-9084-47c8-b0bb-a36fb6353e08'	System	03 Oct 2020 19:01:22
User entered 'Yes (Y)'	System	03 Oct 2020 19:01:22

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T12:01:09', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '53962199-9084-47c8-b0bb-a36fb6353e08'	System	03 Oct 2020 19:01:22
User entered '98.7'	System	03 Oct 2020 19:01:22

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T12:01:14', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '53962199-9084-47c8-b0bb-a36fb6353e08'	System	03 Oct 2020 19:01:22
User entered 'No (N)'	System	03 Oct 2020 19:01:22

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T12:01:17', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '53962199-9084-47c8-b0bb-a36fb6353e08'	System	03 Oct 2020 19:01:22
User entered '03 Oct 2020 12:01'	System	03 Oct 2020 19:01:22

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 3'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-04T12:05:47', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '41dc275a-55b1-4170-a6bf-d28bdb398dde'	System	04 Oct 2020 19:06:00
User entered 'Yes (Y)'	System	04 Oct 2020 19:06:00

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-04T12:05:52', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '41dc275a-55b1-4170-a6bf-d28bdb398dde'	System	04 Oct 2020 19:06:00
User entered '98.5'	System	04 Oct 2020 19:06:00

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-04T12:05:54', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '41dc275a-55b1-4170-a6bf-d28bdb398dde'	System	04 Oct 2020 19:06:00
User entered 'No (N)'	System	04 Oct 2020 19:06:00

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-04T12:05:56', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '41dc275a-55b1-4170-a6bf-d28bdb398dde'	System	04 Oct 2020 19:06:00
User entered '04 Oct 2020 12:05'	System	04 Oct 2020 19:06:00

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 4'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-05T12:01:06', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '635a42f3-cf8e-40ba-8a4b-6d46e1af222f'	System	05 Oct 2020 19:01:22
User entered 'Yes (Y)'	System	05 Oct 2020 19:01:22

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-05T12:01:11', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '635a42f3-cf8e-40ba-8a4b-6d46e1af222f'	System	05 Oct 2020 19:01:22
User entered '98.7'	System	05 Oct 2020 19:01:22

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-05T12:01:13', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '635a42f3-cf8e-40ba-8a4b-6d46e1af222f'	System	05 Oct 2020 19:01:22
User entered 'No (N)'	System	05 Oct 2020 19:01:22

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-05T12:01:16', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '635a42f3-cf8e-40ba-8a4b-6d46e1af222f'	System	05 Oct 2020 19:01:22
User entered '05 Oct 2020 12:01'	System	05 Oct 2020 19:01:22

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 5'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-06T12:00:34', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'fe44e0bd-2e0e-496d-8b5d-9b5aba7627c5'	System	06 Oct 2020 19:00:49
User entered 'Yes (Y)'	System	06 Oct 2020 19:00:49

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-06T12:00:40', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'fe44e0bd-2e0e-496d-8b5d-9b5aba7627c5'	System	06 Oct 2020 19:00:49
User entered '98.5'	System	06 Oct 2020 19:00:49

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-06T12:00:43', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'fe44e0bd-2e0e-496d-8b5d-9b5aba7627c5'	System	06 Oct 2020 19:00:49
User entered 'No (N)'	System	06 Oct 2020 19:00:49

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-06T12:00:46', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'fe44e0bd-2e0e-496d-8b5d-9b5aba7627c5'	System	06 Oct 2020 19:00:49
User entered '06 Oct 2020 12:00'	System	06 Oct 2020 19:00:49

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 6'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-07T12:10:42', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '0c47f5dd-35e2-44f5-8001-61a5b2ccde99'	System	07 Oct 2020 19:11:03
User entered 'Yes (Y)'	System	07 Oct 2020 19:11:03

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-07T12:10:46', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '0c47f5dd-35e2-44f5-8001-61a5b2ccde99'	System	07 Oct 2020 19:11:03
User entered '98.6'	System	07 Oct 2020 19:11:03

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-07T12:10:56', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '0c47f5dd-35e2-44f5-8001-61a5b2ccde99'	System	07 Oct 2020 19:11:03
User entered 'No (N)'	System	07 Oct 2020 19:11:03

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-07T12:10:59', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '0c47f5dd-35e2-44f5-8001-61a5b2ccde99'	System	07 Oct 2020 19:11:03
User entered '07 Oct 2020 12:10'	System	07 Oct 2020 19:11:03

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 7'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-08T12:02:24', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '409fd407-c61b-4a32-a4ee-bb4a08661893'	System	08 Oct 2020 19:02:39
User entered 'Yes (Y)'	System	08 Oct 2020 19:02:39

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-08T12:02:29', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '409fd407-c61b-4a32-a4ee-bb4a08661893'	System	08 Oct 2020 19:02:39
User entered '98.6'	System	08 Oct 2020 19:02:39

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-08T12:02:31', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '409fd407-c61b-4a32-a4ee-bb4a08661893'	System	08 Oct 2020 19:02:39
User entered 'No (N)'	System	08 Oct 2020 19:02:39

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-08T12:02:34', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '409fd407-c61b-4a32-a4ee-bb4a08661893'	System	08 Oct 2020 19:02:39
User entered '08 Oct 2020 12:02'	System	08 Oct 2020 19:02:39

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-02T13:38:35', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '7e84172f-4527-40f6-816d-e8a9f39153db'	System	02 Oct 2020 20:38:54
User entered 'None (1)'	System	02 Oct 2020 20:38:54

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-02T13:38:38', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '7e84172f-4527-40f6-816d-e8a9f39153db'	System	02 Oct 2020 20:38:54
User entered 'No (N)'	System	02 Oct 2020 20:38:54

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-02T13:38:42', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '7e84172f-4527-40f6-816d-e8a9f39153db'	System	02 Oct 2020 20:38:54
User entered 'No (N)'	System	02 Oct 2020 20:38:54

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-02T13:38:46', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '7e84172f-4527-40f6-816d-e8a9f39153db'	System	02 Oct 2020 20:38:54
User entered 'None (1)'	System	02 Oct 2020 20:38:54

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-02T13:38:49', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '7e84172f-4527-40f6-816d-e8a9f39153db'	System	02 Oct 2020 20:38:54
User entered '02 Oct 2020 13:38'	System	02 Oct 2020 20:38:54

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '02 Oct 2020 13:23'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '02 Oct 2020 15:53'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:56:32', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '83d9f902-9f6c-44c4-b77f-783beb6cf648'	System	03 Oct 2020 17:57:02
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 17:57:02

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:56:36', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '83d9f902-9f6c-44c4-b77f-783beb6cf648'	System	03 Oct 2020 17:57:02
User entered 'No (N)'	System	03 Oct 2020 17:57:02

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:56:39', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '83d9f902-9f6c-44c4-b77f-783beb6cf648'	System	03 Oct 2020 17:57:02
User entered 'Yes (Y)'	System	03 Oct 2020 17:57:02

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:56:50', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '83d9f902-9f6c-44c4-b77f-783beb6cf648'	System	03 Oct 2020 17:57:02
User entered '1'	System	03 Oct 2020 17:57:02

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:56:54', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '83d9f902-9f6c-44c4-b77f-783beb6cf648'	System	03 Oct 2020 17:57:02
User entered 'None (1)'	System	03 Oct 2020 17:57:02

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:56:58', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '83d9f902-9f6c-44c4-b77f-783beb6cf648'	System	03 Oct 2020 17:57:02
User entered '03 Oct 2020 10:56'	System	03 Oct 2020 17:57:02

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '02 Oct 2020 16:48'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 2'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T12:02:01', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '2ef7db28-9a25-44ea-b3b2-d94e9d9ee7d5'	System	03 Oct 2020 19:02:18
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 19:02:18

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T12:02:05', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '2ef7db28-9a25-44ea-b3b2-d94e9d9ee7d5'	System	03 Oct 2020 19:02:18
User entered 'No (N)'	System	03 Oct 2020 19:02:18

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T12:02:10', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '2ef7db28-9a25-44ea-b3b2-d94e9d9ee7d5'	System	03 Oct 2020 19:02:18
User entered 'No (N)'	System	03 Oct 2020 19:02:18

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T12:02:13', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '2ef7db28-9a25-44ea-b3b2-d94e9d9ee7d5'	System	03 Oct 2020 19:02:18
User entered 'None (1)'	System	03 Oct 2020 19:02:18

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T12:02:16', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '2ef7db28-9a25-44ea-b3b2-d94e9d9ee7d5'	System	03 Oct 2020 19:02:18
User entered '03 Oct 2020 12:02'	System	03 Oct 2020 19:02:18

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 3'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-04T12:06:01', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '143d157a-c220-4eac-9302-66f2c7fefede'	System	04 Oct 2020 19:06:13
User entered 'None (1)'	System	04 Oct 2020 19:06:13

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-04T12:06:03', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '143d157a-c220-4eac-9302-66f2c7fefede'	System	04 Oct 2020 19:06:13
User entered 'No (N)'	System	04 Oct 2020 19:06:13

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-04T12:06:04', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '143d157a-c220-4eac-9302-66f2c7fefede'	System	04 Oct 2020 19:06:13
User entered 'No (N)'	System	04 Oct 2020 19:06:13

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-04T12:06:06', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '143d157a-c220-4eac-9302-66f2c7fefede'	System	04 Oct 2020 19:06:13
User entered 'None (1)'	System	04 Oct 2020 19:06:13

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-04T12:06:09', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '143d157a-c220-4eac-9302-66f2c7fefede'	System	04 Oct 2020 19:06:13
User entered '04 Oct 2020 12:06'	System	04 Oct 2020 19:06:13

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 4'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-05T12:01:23', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '523f08c1-f283-4d69-b89f-42270c6c50d0'	System	05 Oct 2020 19:01:36
User entered 'None (1)'	System	05 Oct 2020 19:01:36

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-05T12:01:25', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '523f08c1-f283-4d69-b89f-42270c6c50d0'	System	05 Oct 2020 19:01:36
User entered 'No (N)'	System	05 Oct 2020 19:01:36

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-05T12:01:27', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '523f08c1-f283-4d69-b89f-42270c6c50d0'	System	05 Oct 2020 19:01:36
User entered 'No (N)'	System	05 Oct 2020 19:01:36

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-05T12:01:30', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '523f08c1-f283-4d69-b89f-42270c6c50d0'	System	05 Oct 2020 19:01:36
User entered 'None (1)'	System	05 Oct 2020 19:01:36

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-05T12:01:32', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '523f08c1-f283-4d69-b89f-42270c6c50d0'	System	05 Oct 2020 19:01:36
User entered '05 Oct 2020 12:01'	System	05 Oct 2020 19:01:36

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 5'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-06T12:00:51', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '51acb33c-1e13-407f-8564-6faff280b1c3'	System	06 Oct 2020 19:01:07
User entered 'None (1)'	System	06 Oct 2020 19:01:07

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-06T12:00:53', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '51acb33c-1e13-407f-8564-6faff280b1c3'	System	06 Oct 2020 19:01:07
User entered 'No (N)'	System	06 Oct 2020 19:01:07

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-06T12:00:55', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '51acb33c-1e13-407f-8564-6faff280b1c3'	System	06 Oct 2020 19:01:07
User entered 'No (N)'	System	06 Oct 2020 19:01:07

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-06T12:00:57', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '51acb33c-1e13-407f-8564-6faff280b1c3'	System	06 Oct 2020 19:01:07
User entered 'None (1)'	System	06 Oct 2020 19:01:07

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-06T12:00:59', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '51acb33c-1e13-407f-8564-6faff280b1c3'	System	06 Oct 2020 19:01:07
User entered '06 Oct 2020 12:00'	System	06 Oct 2020 19:01:07

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 6'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-07T12:11:04', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '9a1c7440-217f-4397-9dd3-38dda133210b'	System	07 Oct 2020 19:11:16
User entered 'None (1)'	System	07 Oct 2020 19:11:16

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-07T12:11:06', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '9a1c7440-217f-4397-9dd3-38dda133210b'	System	07 Oct 2020 19:11:16
User entered 'No (N)'	System	07 Oct 2020 19:11:16

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-07T12:11:08', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '9a1c7440-217f-4397-9dd3-38dda133210b'	System	07 Oct 2020 19:11:16
User entered 'No (N)'	System	07 Oct 2020 19:11:16

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-07T12:11:10', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '9a1c7440-217f-4397-9dd3-38dda133210b'	System	07 Oct 2020 19:11:16
User entered 'None (1)'	System	07 Oct 2020 19:11:16

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-07T12:11:13', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '9a1c7440-217f-4397-9dd3-38dda133210b'	System	07 Oct 2020 19:11:16
User entered '07 Oct 2020 12:11'	System	07 Oct 2020 19:11:16

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 7'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-08T12:02:38', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '4289a4ea-cb04-49c7-a14d-1d9576914c5c'	System	08 Oct 2020 19:02:54
User entered 'None (1)'	System	08 Oct 2020 19:02:54

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-08T12:02:40', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '4289a4ea-cb04-49c7-a14d-1d9576914c5c'	System	08 Oct 2020 19:02:54
User entered 'No (N)'	System	08 Oct 2020 19:02:54

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-08T12:02:42', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '4289a4ea-cb04-49c7-a14d-1d9576914c5c'	System	08 Oct 2020 19:02:54
User entered 'No (N)'	System	08 Oct 2020 19:02:54

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-08T12:02:44', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '4289a4ea-cb04-49c7-a14d-1d9576914c5c'	System	08 Oct 2020 19:02:54
User entered 'None (1)'	System	08 Oct 2020 19:02:54

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-08T12:02:52', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '4289a4ea-cb04-49c7-a14d-1d9576914c5c'	System	08 Oct 2020 19:02:54
User entered '08 Oct 2020 12:02'	System	08 Oct 2020 19:02:54

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-02T13:38:59', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '8d5f9c13-fb36-4752-aa72-6f6bb440e9d5'	System	02 Oct 2020 20:39:29
User entered 'None (0)'	System	02 Oct 2020 20:39:29

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-02T13:39:02', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '8d5f9c13-fb36-4752-aa72-6f6bb440e9d5'	System	02 Oct 2020 20:39:29
User entered 'None (0)'	System	02 Oct 2020 20:39:29

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-02T13:39:06', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '8d5f9c13-fb36-4752-aa72-6f6bb440e9d5'	System	02 Oct 2020 20:39:29
User entered 'None (0)'	System	02 Oct 2020 20:39:29

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-02T13:39:10', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '8d5f9c13-fb36-4752-aa72-6f6bb440e9d5'	System	02 Oct 2020 20:39:29
User entered 'None (0)'	System	02 Oct 2020 20:39:29

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-02T13:39:13', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '8d5f9c13-fb36-4752-aa72-6f6bb440e9d5'	System	02 Oct 2020 20:39:29
User entered 'None (0)'	System	02 Oct 2020 20:39:29

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-02T13:39:17', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '8d5f9c13-fb36-4752-aa72-6f6bb440e9d5'	System	02 Oct 2020 20:39:29
User entered 'None (0)'	System	02 Oct 2020 20:39:29

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-02T13:39:22', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '8d5f9c13-fb36-4752-aa72-6f6bb440e9d5'	System	02 Oct 2020 20:39:29
User entered 'No (N)'	System	02 Oct 2020 20:39:29

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-02T13:39:25', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '8d5f9c13-fb36-4752-aa72-6f6bb440e9d5'	System	02 Oct 2020 20:39:29
User entered '02 Oct 2020 13:39'	System	02 Oct 2020 20:39:29

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '02 Oct 2020 13:23'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '02 Oct 2020 15:53'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:57:03', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '56dcd9c3-b61f-4939-95d6-929e7aa6e694'	System	03 Oct 2020 17:57:34
User entered 'None (0)'	System	03 Oct 2020 17:57:34

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:57:06', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '56dcd9c3-b61f-4939-95d6-929e7aa6e694'	System	03 Oct 2020 17:57:34
User entered 'None (0)'	System	03 Oct 2020 17:57:34

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:57:12', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '56dcd9c3-b61f-4939-95d6-929e7aa6e694'	System	03 Oct 2020 17:57:34
User entered 'None (0)'	System	03 Oct 2020 17:57:34

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:57:14', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '56dcd9c3-b61f-4939-95d6-929e7aa6e694'	System	03 Oct 2020 17:57:34
User entered 'None (0)'	System	03 Oct 2020 17:57:34

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:57:17', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '56dcd9c3-b61f-4939-95d6-929e7aa6e694'	System	03 Oct 2020 17:57:34
User entered 'None (0)'	System	03 Oct 2020 17:57:34

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:57:19', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '56dcd9c3-b61f-4939-95d6-929e7aa6e694'	System	03 Oct 2020 17:57:34
User entered 'None (0)'	System	03 Oct 2020 17:57:34

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:57:27', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '56dcd9c3-b61f-4939-95d6-929e7aa6e694'	System	03 Oct 2020 17:57:34
User entered 'No (N)'	System	03 Oct 2020 17:57:34

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T10:57:29', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '56dcd9c3-b61f-4939-95d6-929e7aa6e694'	System	03 Oct 2020 17:57:34
User entered '03 Oct 2020 10:57'	System	03 Oct 2020 17:57:34

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '02 Oct 2020 16:48'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 2'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T12:01:24', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'b68cf568-4290-4475-b2d9-5d15a8672f08'	System	03 Oct 2020 19:01:56
User entered 'None (0)'	System	03 Oct 2020 19:01:56

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T12:01:31', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'b68cf568-4290-4475-b2d9-5d15a8672f08'	System	03 Oct 2020 19:01:56
User entered 'None (0)'	System	03 Oct 2020 19:01:56

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T12:01:34', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'b68cf568-4290-4475-b2d9-5d15a8672f08'	System	03 Oct 2020 19:01:56
User entered 'None (0)'	System	03 Oct 2020 19:01:56

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T12:01:37', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'b68cf568-4290-4475-b2d9-5d15a8672f08'	System	03 Oct 2020 19:01:56
User entered 'None (0)'	System	03 Oct 2020 19:01:56

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T12:01:41', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'b68cf568-4290-4475-b2d9-5d15a8672f08'	System	03 Oct 2020 19:01:56
User entered 'None (0)'	System	03 Oct 2020 19:01:56

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T12:01:43', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'b68cf568-4290-4475-b2d9-5d15a8672f08'	System	03 Oct 2020 19:01:56
User entered 'None (0)'	System	03 Oct 2020 19:01:56

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T12:01:48', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'b68cf568-4290-4475-b2d9-5d15a8672f08'	System	03 Oct 2020 19:01:56
User entered 'No (N)'	System	03 Oct 2020 19:01:56

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-03T12:01:51', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'b68cf568-4290-4475-b2d9-5d15a8672f08'	System	03 Oct 2020 19:01:56
User entered '03 Oct 2020 12:01'	System	03 Oct 2020 19:01:56

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 3'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-04T12:06:13', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '410b79f6-54e6-46d1-93ac-a2743bc57e0f'	System	04 Oct 2020 19:06:28
User entered 'None (0)'	System	04 Oct 2020 19:06:28

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-04T12:06:14', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '410b79f6-54e6-46d1-93ac-a2743bc57e0f'	System	04 Oct 2020 19:06:28
User entered 'None (0)'	System	04 Oct 2020 19:06:28

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-04T12:06:15', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '410b79f6-54e6-46d1-93ac-a2743bc57e0f'	System	04 Oct 2020 19:06:28
User entered 'None (0)'	System	04 Oct 2020 19:06:28

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-04T12:06:17', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '410b79f6-54e6-46d1-93ac-a2743bc57e0f'	System	04 Oct 2020 19:06:28
User entered 'None (0)'	System	04 Oct 2020 19:06:28

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-04T12:06:19', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '410b79f6-54e6-46d1-93ac-a2743bc57e0f'	System	04 Oct 2020 19:06:28
User entered 'None (0)'	System	04 Oct 2020 19:06:28

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-04T12:06:20', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '410b79f6-54e6-46d1-93ac-a2743bc57e0f'	System	04 Oct 2020 19:06:28
User entered 'None (0)'	System	04 Oct 2020 19:06:28

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-04T12:06:22', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '410b79f6-54e6-46d1-93ac-a2743bc57e0f'	System	04 Oct 2020 19:06:28
User entered 'No (N)'	System	04 Oct 2020 19:06:28

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-04T12:06:25', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '410b79f6-54e6-46d1-93ac-a2743bc57e0f'	System	04 Oct 2020 19:06:28
User entered '04 Oct 2020 12:06'	System	04 Oct 2020 19:06:28

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 4'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-05T12:01:38', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '26613132-cce5-4b7d-8388-cc61c440bd0d'	System	05 Oct 2020 19:01:55
User entered 'None (0)'	System	05 Oct 2020 19:01:55

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-05T12:01:40', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '26613132-cce5-4b7d-8388-cc61c440bd0d'	System	05 Oct 2020 19:01:55
User entered 'None (0)'	System	05 Oct 2020 19:01:55

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-05T12:01:42', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '26613132-cce5-4b7d-8388-cc61c440bd0d'	System	05 Oct 2020 19:01:55
User entered 'None (0)'	System	05 Oct 2020 19:01:55

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-05T12:01:44', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '26613132-cce5-4b7d-8388-cc61c440bd0d'	System	05 Oct 2020 19:01:55
User entered 'None (0)'	System	05 Oct 2020 19:01:55

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-05T12:01:46', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '26613132-cce5-4b7d-8388-cc61c440bd0d'	System	05 Oct 2020 19:01:55
User entered 'None (0)'	System	05 Oct 2020 19:01:55

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-05T12:01:47', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '26613132-cce5-4b7d-8388-cc61c440bd0d'	System	05 Oct 2020 19:01:55
User entered 'None (0)'	System	05 Oct 2020 19:01:55

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-05T12:01:49', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '26613132-cce5-4b7d-8388-cc61c440bd0d'	System	05 Oct 2020 19:01:55
User entered 'No (N)'	System	05 Oct 2020 19:01:55

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-05T12:01:51', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '26613132-cce5-4b7d-8388-cc61c440bd0d'	System	05 Oct 2020 19:01:55
User entered '05 Oct 2020 12:01'	System	05 Oct 2020 19:01:55

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 5'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-06T12:01:06', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'b5f013ec-3592-4e24-ac29-181059c16024'	System	06 Oct 2020 19:01:29
User entered 'None (0)'	System	06 Oct 2020 19:01:29

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-06T12:01:09', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'b5f013ec-3592-4e24-ac29-181059c16024'	System	06 Oct 2020 19:01:29
User entered 'None (0)'	System	06 Oct 2020 19:01:29

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-06T12:01:11', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'b5f013ec-3592-4e24-ac29-181059c16024'	System	06 Oct 2020 19:01:29
User entered 'None (0)'	System	06 Oct 2020 19:01:29

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-06T12:01:13', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'b5f013ec-3592-4e24-ac29-181059c16024'	System	06 Oct 2020 19:01:29
User entered 'None (0)'	System	06 Oct 2020 19:01:29

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-06T12:01:15', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'b5f013ec-3592-4e24-ac29-181059c16024'	System	06 Oct 2020 19:01:29
User entered 'None (0)'	System	06 Oct 2020 19:01:29

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-06T12:01:17', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'b5f013ec-3592-4e24-ac29-181059c16024'	System	06 Oct 2020 19:01:29
User entered 'None (0)'	System	06 Oct 2020 19:01:29

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-06T12:01:20', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'b5f013ec-3592-4e24-ac29-181059c16024'	System	06 Oct 2020 19:01:29
User entered 'No (N)'	System	06 Oct 2020 19:01:29

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-06T12:01:23', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'b5f013ec-3592-4e24-ac29-181059c16024'	System	06 Oct 2020 19:01:29
User entered '06 Oct 2020 12:01'	System	06 Oct 2020 19:01:29

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 6'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-07T12:11:17', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'e4021ca1-3e5a-4395-b308-88cdaf9e22e9'	System	07 Oct 2020 19:11:36
User entered 'None (0)'	System	07 Oct 2020 19:11:36

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-07T12:11:19', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'e4021ca1-3e5a-4395-b308-88cdaf9e22e9'	System	07 Oct 2020 19:11:36
User entered 'None (0)'	System	07 Oct 2020 19:11:36

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-07T12:11:21', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'e4021ca1-3e5a-4395-b308-88cdaf9e22e9'	System	07 Oct 2020 19:11:36
User entered 'None (0)'	System	07 Oct 2020 19:11:36

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-07T12:11:22', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'e4021ca1-3e5a-4395-b308-88cdaf9e22e9'	System	07 Oct 2020 19:11:36
User entered 'None (0)'	System	07 Oct 2020 19:11:36

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-07T12:11:24', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'e4021ca1-3e5a-4395-b308-88cdaf9e22e9'	System	07 Oct 2020 19:11:36
User entered 'None (0)'	System	07 Oct 2020 19:11:36

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-07T12:11:26', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'e4021ca1-3e5a-4395-b308-88cdaf9e22e9'	System	07 Oct 2020 19:11:36
User entered 'None (0)'	System	07 Oct 2020 19:11:36

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-07T12:11:31', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'e4021ca1-3e5a-4395-b308-88cdaf9e22e9'	System	07 Oct 2020 19:11:36
User entered 'No (N)'	System	07 Oct 2020 19:11:36

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-07T12:11:34', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: 'e4021ca1-3e5a-4395-b308-88cdaf9e22e9'	System	07 Oct 2020 19:11:36
User entered '07 Oct 2020 12:11'	System	07 Oct 2020 19:11:36

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	02 Oct 2020 20:19:21
User entered 'Day 7'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-08T12:02:55', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '5b7ce464-6240-495a-82a8-9c270fcc3d73'	System	08 Oct 2020 19:03:12
User entered 'None (0)'	System	08 Oct 2020 19:03:12

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-08T12:02:57', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '5b7ce464-6240-495a-82a8-9c270fcc3d73'	System	08 Oct 2020 19:03:12
User entered 'None (0)'	System	08 Oct 2020 19:03:12

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-08T12:02:59', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '5b7ce464-6240-495a-82a8-9c270fcc3d73'	System	08 Oct 2020 19:03:12
User entered 'None (0)'	System	08 Oct 2020 19:03:12

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-08T12:03:01', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '5b7ce464-6240-495a-82a8-9c270fcc3d73'	System	08 Oct 2020 19:03:12
User entered 'None (0)'	System	08 Oct 2020 19:03:12

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-08T12:03:02', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '5b7ce464-6240-495a-82a8-9c270fcc3d73'	System	08 Oct 2020 19:03:12
User entered 'None (0)'	System	08 Oct 2020 19:03:12

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-08T12:03:04', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '5b7ce464-6240-495a-82a8-9c270fcc3d73'	System	08 Oct 2020 19:03:12
User entered 'None (0)'	System	08 Oct 2020 19:03:12

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

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 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-08T12:03:07', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '5b7ce464-6240-495a-82a8-9c270fcc3d73'	System	08 Oct 2020 19:03:12
User entered 'No (N)'	System	08 Oct 2020 19:03:12

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-10-08T12:03:09', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '5b7ce464-6240-495a-82a8-9c270fcc3d73'	System	08 Oct 2020 19:03:12
User entered '08 Oct 2020 12:03'	System	08 Oct 2020 19:03:12

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 20:19:21

US3882016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 20:19:21

US3882016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:47:38
User signature succeeded.	Michael Lewis (b) (4)	09 Oct 2020 23:49:31
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	09 Oct 2020 18:03:33

US3882016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:47:38
User signature succeeded.	Michael Lewis (b) (4)	09 Oct 2020 23:49:31
User entered '09 Oct 2020'	Lauren Vigil (b) (4)	09 Oct 2020 18:03:33

US3882016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:47:38
User signature succeeded.	Michael Lewis (b) (4)	09 Oct 2020 23:49:31
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	09 Oct 2020 18:03:33

US3882016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:47:38
User signature succeeded.	Michael Lewis (b) (4)	09 Oct 2020 23:49:31
User entered empty.	Lauren Vigil (b) (4)	09 Oct 2020 18:03:33
	(b) (4)	

US3882016

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:47:45
User signature succeeded.	Michael Lewis (b) (4)	09 Oct 2020 23:49:31
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	09 Oct 2020 18:03:43

US3882016

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'I'	System	09 Oct 2020 18:03:43

US3882016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:48:06
User signature succeeded.	Michael Lewis (b) (4)	16 Oct 2020 23:13:28
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	16 Oct 2020 21:52:19

US3882016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:48:06
User signature succeeded.	Michael Lewis (b) (4)	16 Oct 2020 23:13:28
User entered '16 Oct 2020'	Lauren Vigil (b) (4)	16 Oct 2020 21:52:19

US3882016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:48:06
User signature succeeded.	Michael Lewis (b) (4)	16 Oct 2020 23:13:28
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	16 Oct 2020 21:52:19

US3882016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:48:06
User signature succeeded.	Michael Lewis (b) (4)	16 Oct 2020 23:13:28
User entered empty.	Lauren Vigil (b) (4)	16 Oct 2020 21:52:19
	(b) (4)	

US3882016

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:48:12
User signature succeeded.	Michael Lewis (b) (4)	16 Oct 2020 23:13:28
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	16 Oct 2020 21:52:26

US3882016

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'I'	System	16 Oct 2020 21:52:26

US3882016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:48:33
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:12:22
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	26 Oct 2020 18:05:02

US3882016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	30 Jan 2021 00:49:08
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 10:23:55
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:12:22
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Contact was attempted but not made until Oct. 27th 2020' (Site from System).	Lauren Vigil (b) (4)	27 Oct 2020 22:00:38
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	27 Oct 2020 21:49:52
User entered '27 Oct 2020' reason for change: Data Entry Error	Lauren Vigil (b) (4)	27 Oct 2020 21:49:52
User entered '26 Oct 2020'	Suchi Tiwari (b) (4)	26 Oct 2020 18:05:02

US3882016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:48:31
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:12:22
User entered 'Contact Made (CONTACT MADE)'	Suchi Tiwari (b) (4)	26 Oct 2020 18:05:02

US3882016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	30 Jan 2021 00:47:59
User closed query 'Per DM CLR: Comment = ALOGLIPTIN PO DOSE INCREASED BY PCP TODAY, however, there is no recorded changes in the dose of the corresponding ConMed. Please reconcile and update to record the change in dose as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 12:58:33
User closed query 'Per DM CLR: Comment = IMAGING AND EKG UNREMARKABLE. Review if this procedure should also be captured on Concomitant Procedure page. If yes, please update Concomitant Procedure page as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 12:58:25
User closed query 'Per DM CLR: Review specified comment, + CHEST PAIN REQUIRING ED VISIT ON 10/26. Verify if this condition meets AE reporting criteria. If yes, update AE page as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 12:39:43
Query 'Per DM CLR: Comment = ALOGLIPTIN PO DOSE INCREASED BY PCP TODAY, however, there is no recorded changes in the dose of the corresponding ConMed. Please reconcile and update to record the change in dose as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	30 Nov 2020 20:08:26
Query 'Per DM CLR: Comment = IMAGING AND EKG UNREMARKABLE. Review if this procedure should also be captured on Concomitant Procedure page. If yes, please update Concomitant Procedure page as appropriate.' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	30 Nov 2020 20:06:47
Query 'Per DM CLR: Review specified comment, + CHEST PAIN REQUIRING ED VISIT ON 10/26. Verify if this condition meets AE reporting criteria. If yes, update AE page as appropriate.' answered with 'AE added' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	30 Nov 2020 20:06:11

US3882016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Comment = ALOGLIPTIN PO DOSE INCREASED BY PCP TODAY, however, there is no recorded changes in the dose of the corresponding ConMed. Please reconcile and update to record the change in dose as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 10:00:25
User opened query 'Per DM CLR: Comment = IMAGING AND EKG UNREMARKABLE. Review if this procedure should also be captured on Concomitant Procedure page. If yes, please update Concomitant Procedure page as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 10:00:13
User opened query 'Per DM CLR: Review specified comment, + CHEST PAIN REQUIRING ED VISIT ON 10/26. Verify if this condition meets AE reporting criteria. If yes, update AE page as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 10:00:04
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:12:22
User entered '+ chest pain requiring ED visit on 10/26. Imaging and EKG unremarkable. Blood glucose >300 mg/dl. Alogliptin PO dose increased by PCP today' reason for change: Data Entry Error	Lauren Vigil (b) (4)	27 Oct 2020 21:51:56
User entered empty.	Suchi Tiwari (b) (4)	26 Oct 2020 18:05:02

US3882016

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:48:51
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:12:22
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	27 Oct 2020 21:50:00

US3882016

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'I'	System	27 Oct 2020 21:50:00

US3882016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:03
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User entered 'Yes (Y)'	Sara Wong (b) (4)	30 Oct 2020 20:52:21

US3882016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:03
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User entered '30 Oct 2020'	Sara Wong (b) (4)	30 Oct 2020 20:52:21

US3882016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:03
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User entered 'Clinic (Clinic)'	Sara Wong (b) (4)	30 Oct 2020 20:52:21

US3882016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'VISIT3'	System	30 Oct 2020 20:52:21

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:26
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User entered 'Yes (Y)'	Sara Wong (b) (4)	30 Oct 2020 20:52:49

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:26
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User entered '30 Oct 2020'	Sara Wong (b) (4)	30 Oct 2020 20:52:49

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:26
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User entered '12:15'	Sara Wong (b) (4)	30 Oct 2020 20:52:49

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '30 Oct 2020 12:15'	System	30 Oct 2020 20:52:49

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:26
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User entered '98.3' F	Sara Wong (b) (4)	30 Oct 2020 20:52:49

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:26
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User entered 'Oral (Oral)'	Sara Wong (b) (4)	30 Oct 2020 20:52:49

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:26
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User entered empty.	Sara Wong (b) (4)	30 Oct 2020 20:52:49

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:26
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User entered '93'	Sara Wong (b) (4)	30 Oct 2020 20:52:49

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'bpm'	System	30 Oct 2020 20:52:49

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:26
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User entered '15'	Sara Wong (b) (4)	30 Oct 2020 20:52:49

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'breaths/min'	System	30 Oct 2020 20:52:49

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:26
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Oct 2020 20:54:03
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	30 Oct 2020 20:54:03
User entered '123' reason for change: Data Entry Error	Sara Wong (b) (4)	30 Oct 2020 20:54:03
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Oct 2020 20:52:49
User entered '12'	Sara Wong (b) (4)	30 Oct 2020 20:52:49

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'mmHg'	System	30 Oct 2020 20:52:49

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:26
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Oct 2020 20:54:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	30 Oct 2020 20:54:03
User entered '84' reason for change: Data Entry Error	Sara Wong (b) (4)	30 Oct 2020 20:54:03
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Oct 2020 20:52:49
User entered empty.	Sara Wong (b) (4)	30 Oct 2020 20:52:49

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'mmHg'	System	30 Oct 2020 20:54:03
User entered empty.	System	30 Oct 2020 20:52:49

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00

US3882016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00

US3882016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:39
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User entered 'Yes (Y)'	Sara Wong (b) (4)	30 Oct 2020 20:54:10

US3882016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:39
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User entered '30 Oct 2020'	Sara Wong (b) (4)	30 Oct 2020 20:54:10

US3882016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:29

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:53
User closed query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 30OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:17:41
Query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 30OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' answered with 'sample was collected' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	09 Nov 2020 17:23:53
User opened query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 30OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 19:04:58
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User entered 'Yes (Y)'	Sara Wong (b) (4) (b) (4)	30 Oct 2020 20:54:53

US3882016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:53
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User entered '30 Oct 2020'	Sara Wong (b) (4)	30 Oct 2020 20:54:53

US3882016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:49:53
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User entered '12:50'	Sara Wong (b) (4)	30 Oct 2020 20:54:53

US3882016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '30 Oct 2020 12:50'	System	30 Oct 2020 20:54:53

US3882016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:50:00
User signature succeeded.	Michael Lewis (b) (4)	31 Oct 2020 01:21:38
User entered 'Yes (Y)'	Sara Wong (b) (4)	30 Oct 2020 20:54:57

US3882016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'I'	System	30 Oct 2020 20:54:57

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 64'	System	05 Sep 2020 21:00:53

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-11-04T11:12:39', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '1f0b5d19-eb36-40a8-9bfd-813fded53937'	System	04 Nov 2020 19:12:53
User entered 'No (N)'	System	04 Nov 2020 19:12:53

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-11-04T11:12:44', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '1f0b5d19-eb36-40a8-9bfd-813fded53937'	System	04 Nov 2020 19:12:53
User entered 'No (N)'	System	04 Nov 2020 19:12:53

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-11-04T11:12:50', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '1f0b5d19-eb36-40a8-9bfd-813fded53937'	System	04 Nov 2020 19:12:53
User entered '04 Nov 2020 11:12:50'	System	04 Nov 2020 19:12:53

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered '04 Nov 2020 00:01'	System	05 Sep 2020 21:00:53

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered '08 Nov 2020 23:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 71'	System	05 Sep 2020 21:00:53

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-11-11T14:53:15', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '5cd87ba0-b84e-481a-90b8-6d97207fa9f5'	System	11 Nov 2020 22:53:29
User entered 'No (N)'	System	11 Nov 2020 22:53:29

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-11-11T14:53:18', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '5cd87ba0-b84e-481a-90b8-6d97207fa9f5'	System	11 Nov 2020 22:53:29
User entered 'No (N)'	System	11 Nov 2020 22:53:29

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7d75ac80268e94a9)', Time: '2020-11-11T14:53:22', User OID: 'PatientReportedOutcome (US3882016)', ODM File OID: '5cd87ba0-b84e-481a-90b8-6d97207fa9f5'	System	11 Nov 2020 22:53:29
User entered '11 Nov 2020 14:53:22'	System	11 Nov 2020 22:53:29

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered '11 Nov 2020 00:01'	System	05 Sep 2020 21:00:53

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:58
Data entry locked.	System	05 Sep 2020 21:00:53
User entered '15 Nov 2020 23:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15
Data entry locked.	System	05 Sep 2020 21:00:53
User entered 'Day 78'	System	05 Sep 2020 21:00:53

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15
Data entry locked.	System	05 Sep 2020 21:00:53
User entered '18 Nov 2020 00:01'	System	05 Sep 2020 21:00:53

US3882016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:41:15
Data entry locked.	System	05 Sep 2020 21:00:53
User entered '22 Nov 2020 23:59'	System	05 Sep 2020 21:00:53

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 03:41:15

US3882016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
Amendment Manager: DataPoint Activated.	System	15 Apr 2021 02:12:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:09:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:41:15
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 03:41:15

US3882016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 06:24:05
User signature succeeded.	Michael Lewis (b) (4)	05 Jan 2021 04:10:25
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	30 Dec 2020 20:55:24

US3882016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:23:26
User closed query 'Source indicates call was made on 28Nov2020. Please confirm and update source and EDC as needed. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 19:23:24
Query 'Source indicates call was made on 28Nov2020. Please confirm and update source and EDC as needed. ' answered with 'updated' (Site from CRA).	Lauren Vigil (b) (4)	02 Feb 2021 16:21:42
Signature has been broken.	Lauren Vigil (b) (4)	02 Feb 2021 16:21:37
User entered '28 Nov 2020' reason for change: Data Entry Error	Lauren Vigil (b) (4)	02 Feb 2021 16:21:37
User opened query 'Source indicates call was made on 28Nov2020. Please confirm and update source and EDC as needed. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 06:24:02
User signature succeeded.	Michael Lewis (b) (4)	05 Jan 2021 04:10:25
User entered '27 Nov 2020'	Lauren Vigil (b) (4)	30 Dec 2020 20:55:24

US3882016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 06:37:35
Query 'Please confirm if contact was not successful and if 3 attempts were made. ' canceled (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 06:37:33
User opened query 'Please confirm if contact was not successful and if 3 attempts were made. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 06:24:59
User signature succeeded.	Michael Lewis (b) (4)	05 Jan 2021 04:10:25
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lauren Vigil (b) (4)	30 Dec 2020 20:55:24

US3882016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:07:46
User closed query 'If contact was not made, please update comment to "3 attempts were made but contact was not successful" ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 19:07:22
Query 'If contact was not made, please update comment to "3 attempts were made but contact was not successful" ' answered with 'updated' (Site from CRA).	Lauren Vigil (b) (4)	02 Feb 2021 16:21:46
Signature has been broken.	Lauren Vigil (b) (4)	02 Feb 2021 16:21:37
User entered '3 attempts were made but contact was not successful' reason for change: Data Entry Error	Lauren Vigil (b) (4)	02 Feb 2021 16:21:37
User opened query 'If contact was not made, please update comment to "3 attempts were made but contact was not successful" ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 06:36:29
User signature succeeded.	Michael Lewis (b) (4)	05 Jan 2021 04:10:25
User entered 'WILL CONTINUE TO ATTEMPT'	Lauren Vigil (b) (4)	30 Dec 2020 20:55:24

US3882016

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 06:28:42
User signature succeeded.	Michael Lewis (b) (4)	05 Jan 2021 04:10:25
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	30 Dec 2020 20:55:29

US3882016

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'I'	System	30 Dec 2020 20:55:29

US3882016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 06:29:38
User signature succeeded.	Michael Lewis (b) (4)	05 Jan 2021 04:10:25
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	30 Dec 2020 21:02:59

US3882016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	22 Feb 2021 23:26:17
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:53:35
User closed query 'Source indicates call was made on 31Dec2020. Please reconcile as update source and EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 17:53:31
Query 'Source indicates call was made on 31Dec2020. Please reconcile as update source and EDC as needed.' answered with 'updated' (Site from CRA).	Lauren Vigil (b) (4)	19 Feb 2021 17:14:24
Signature has been broken.	Lauren Vigil (b) (4)	19 Feb 2021 17:13:50
User entered '31 Dec 2020' reason for change: Data Entry Error	Lauren Vigil (b) (4)	19 Feb 2021 17:13:50
User opened query 'Source indicates call was made on 31Dec2020. Please reconcile as update source and EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 06:29:34
User signature succeeded.	Michael Lewis (b) (4)	05 Jan 2021 04:10:25
User entered '30 Dec 2020'	Lauren Vigil (b) (4)	30 Dec 2020 21:02:59

US3882016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 06:29:40
User signature succeeded.	Michael Lewis (b) (4)	05 Jan 2021 04:10:25
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	30 Dec 2020 21:02:59

US3882016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 04:09:56
User signature succeeded.	Michael Lewis (b) (4)	06 Mar 2021 23:05:40
User closed query 'Per DM CLR: Please review if + BODY ACHES is considered an AE event and should be recorded in AE ecrf. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 09:51:52
Query 'Per DM CLR: Please review if + BODY ACHES is considered an AE event and should be recorded in AE ecrf. Review and update as appropriate. ' answered with 'entered in error' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	25 Feb 2021 22:48:27
DataPoint Un-verified.	Lauren Vigil (b) (4) (b) (4)	25 Feb 2021 22:48:24
Signature has been broken.	Lauren Vigil (b) (4) (b) (4)	25 Feb 2021 22:48:24
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4) (b) (4)	25 Feb 2021 22:48:24
User opened query 'Per DM CLR: Please review if + BODY ACHES is considered an AE event and should be recorded in AE ecrf. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 21:40:01
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:53:41
User signature succeeded.	Michael Lewis (b) (4)	05 Jan 2021 04:10:25
User entered '+ body aches'	Lauren Vigil (b) (4) (b) (4)	30 Dec 2020 21:02:59

US3882016

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 06:29:52
User signature succeeded.	Michael Lewis (b) (4)	05 Jan 2021 04:10:25
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	30 Dec 2020 21:03:03

US3882016

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'I'	System	30 Dec 2020 21:03:03

US3882016

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 04:49:06
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'Yes (Y)'	Justine Velandria (b) (4)	02 Feb 2021 00:23:17

US3882016

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 04:10:22
User closed query 'Source notes date of contact was made on 26Jan2021. Please reconcile as needed.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 04:10:20
Query 'Source notes date of contact was made on 26Jan2021. Please reconcile as needed.' answered with 'Source updated.' (Site from CRA).	Lauren Vigil (b) (4)	09 Mar 2021 17:26:03
User opened query 'Source notes date of contact was made on 26Jan2021. Please reconcile as needed.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 04:50:00
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	02 Feb 2021 00:23:29
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	02 Feb 2021 00:23:29
User entered '28 Jan 2021' reason for change: Data Entry Error	Justine Velandria (b) (4)	02 Feb 2021 00:23:29
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	02 Feb 2021 00:23:17
User entered '26 Jan 2021'	Justine Velandria (b) (4)	02 Feb 2021 00:23:17

US3882016

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 04:49:07
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'Contact Made (CONTACT MADE)'	Justine Velandria (b) (4) (b) (4)	02 Feb 2021 00:23:17

US3882016

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 04:49:10
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'Denies fever, chills, cough, sore throat, malaise, headache, olfactory/gustatory changes, or n/v. Denies known exposure to C19. Denies changes in rx list'	Justine Velandria (b) (4)	02 Feb 2021 00:23:17

US3882016

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 04:50:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'Yes (Y)'	Justine Velandria (b) (4)	02 Feb 2021 00:23:34

US3882016

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'I'	System	02 Feb 2021 00:23:34

US3882016

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 19:40:15
User signature succeeded.	Michael Lewis (b) (4)	06 Mar 2021 23:05:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 19:32:28

US3882016

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 19:40:15
User signature succeeded.	Michael Lewis (b) (4)	06 Mar 2021 23:05:40
User entered '1 Mar 2021'	(b) (4), (b) (6)	01 Mar 2021 19:32:28

US3882016

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 19:40:15
User signature succeeded.	Michael Lewis (b) (4)	06 Mar 2021 23:05:40
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	01 Mar 2021 19:32:28

US3882016

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 19:40:15
User signature succeeded.	Michael Lewis (b) (4)	06 Mar 2021 23:05:40
User entered 'Left voicemail'	(b) (4), (b) (6)	01 Mar 2021 19:32:28

US3882016

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 19:40:42
User signature succeeded.	Michael Lewis (b) (4)	06 Mar 2021 23:05:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 19:32:33

US3882016

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered 'I'	System	01 Mar 2021 19:32:33

US3882016

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

Form: Unblinding

Generated On: 10 Jun 2021 10:17:29

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	01 Apr 2021 19:55:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:17:19
User entered empty.	Lauren Vigil (b) (4)	31 Mar 2021 15:34:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 15:29:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:06:49

US3882016

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

Form: Unblinding

Generated On: 10 Jun 2021 10:17:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	01 Apr 2021 19:55:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:17:19
User entered 'I'	Lauren Vigil (b) (4)	31 Mar 2021 15:34:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 15:29:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:06:49
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:35:03

US3882016

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

Form: Unblinding

Generated On: 10 Jun 2021 10:17:29

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	01 Apr 2021 19:55:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:17:19
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	31 Mar 2021 15:34:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 15:29:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:06:49

US3882016

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

Form: Unblinding

Generated On: 10 Jun 2021 10:17:29

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	01 Apr 2021 19:55:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:17:19
User entered 'Amendment 5 (Amendment 5)'	Lauren Vigil (b) (4)	31 Mar 2021 15:34:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 15:29:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:06:49
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:35:03

US3882016

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

Form: Unblinding

Generated On: 10 Jun 2021 10:17:29

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	01 Apr 2021 19:55:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:17:19
User entered '4 Mar 2021'	Lauren Vigil (b) (4)	31 Mar 2021 15:34:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 15:29:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:06:49

US3882016

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

Form: Unblinding

Generated On: 10 Jun 2021 10:17:29

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	01 Apr 2021 19:55:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:17:19
User entered 'mRNA-1273 (mRNA-1273)'	Lauren Vigil (b) (4)	31 Mar 2021 15:34:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 15:29:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:06:49

US3882016

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

Form: Unblinding

Generated On: 10 Jun 2021 10:17:29

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	01 Apr 2021 19:55:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:17:19
User entered 'mRNA-1273 (mRNA-1273)'	Lauren Vigil (b) (4)	31 Mar 2021 15:34:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 15:29:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:06:49

US3882016

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

Form: Unblinding

Generated On: 10 Jun 2021 10:17:29

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	01 Apr 2021 19:55:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:17:19
User entered 'mRNA-1273 (mRNA-1273)'	Lauren Vigil (b) (4)	31 Mar 2021 15:34:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 15:29:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:06:49

US3882016

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

Form: Unblinding

Generated On: 10 Jun 2021 10:17:29

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	01 Apr 2021 19:55:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:17:19
User entered 'No (N)'	Lauren Vigil (b) (4)	31 Mar 2021 15:34:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 15:29:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:06:49

US3882016

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

Form: Unblinding

Generated On: 10 Jun 2021 10:17:29

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	31 Mar 2021 15:34:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 15:29:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:06:49

US3882016

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

Form: Unblinding

Generated On: 10 Jun 2021 10:17:29

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	31 Mar 2021 15:34:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 15:29:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Mar 2021 21:06:49

US3882016

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:17:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 06:42:52
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
Signature has been broken.	Lauren Vigil (b) (4)	30 Nov 2020 20:05:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	30 Nov 2020 20:05:07
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 22:04:40

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:46

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
User closed query 'Per DM CLR: Please review AE and please update to specify whether Chest Pain is Cardiac or Musculoskeletal or Respiratory -related condition. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify,' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 06:15:03
Query 'Per DM CLR: Please review AE and please update to specify whether Chest Pain is Cardiac or Musculoskeletal or Respiratory -related condition. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify,' answered with 'Musculoskeletal-related' (Site from DM).	Justine Velandria (b) (4) (b) (4)	15 Mar 2021 16:17:23
User opened query 'Per DM CLR: Please review AE and please update to specify whether Chest Pain is Cardiac or Musculoskeletal or Respiratory -related condition. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify,' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 15:18:26
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 18:50:18
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Subject was not assessed' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	19 Feb 2021 17:09:53
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:29:39
User signature succeeded.	Michael Lewis (b) (4)	05 Jan 2021 04:10:25

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 04:47:17
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Generalised chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	22 Dec 2020 15:32:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	22 Dec 2020 00:59:12
Coding entries removed.	Lauren Vigil (b) (4)	22 Dec 2020 00:59:00
	(b) (4)	
Signature has been broken.	Lauren Vigil (b) (4)	22 Dec 2020 00:59:00
	(b) (4)	
User entered 'CHEST PAIN (general pain and discomfort)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	22 Dec 2020 00:59:00
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	(b) (4)	
' answered with 'general pain and discomfort' (Site from DM).	Lauren Vigil (b) (4)	22 Dec 2020 00:58:53
	(b) (4)	
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	(b) (4), (b) (6)	22 Dec 2020 00:56:56
' (Site from DM).		

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	30 Nov 2020 20:07:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Nov 2020 20:07:04
Data point term sent to Coder	System	30 Nov 2020 20:06:51
User entered 'CHEST PAIN'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered 'No (N)'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered 'No (N)'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered '26 Oct 2020'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered empty.	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
User entered empty.	System	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered 'No (N)'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered '26 Oct 2020'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered empty.	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
User entered empty.	System	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered 'Grade 1/Mild (Grade 1/Mild)'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered 'No (N)'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered '0'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered '0'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered '0'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered empty.	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered empty.	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered empty.	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered empty.	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered '0'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered '0'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered '0'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered 'Not Related (NOT RELATED)'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered 'Not Related (NOT RELATED)'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	05 Jan 2021 04:10:25
User closed query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 02 Oct 2020 and AE#1 has a start date 26 Oct 2020. Per pages 42-43 of CCGs version 3.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 06:05:31
Query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 02 Oct 2020 and AE#1 has a start date 26 Oct 2020. Per pages 42-43 of CCGs version 3.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	30 Dec 2020 20:33:29
Signature has been broken.	Lauren Vigil (b) (4)	30 Dec 2020 20:33:24
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	30 Dec 2020 20:33:24
User opened query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 02 Oct 2020 and AE#1 has a start date 26 Oct 2020. Per pages 42-43 of CCGs version 3.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 10:23:13
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered 'None (NONE)'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
User signature succeeded.	Michael Lewis (b) (4)	20 Mar 2021 23:11:03
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:17:19
DataPoint Un-verified.	(b) (4), (b) (6)	20 Mar 2021 21:12:59
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:12:22
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Mar 2021 16:18:25
DataPoint Un-verified.	Justine Velandria (b) (4)	15 Mar 2021 16:18:25
Signature has been broken.	Justine Velandria (b) (4)	15 Mar 2021 16:18:25
User entered '1' reason for change: Data Entry Error	Justine Velandria (b) (4)	15 Mar 2021 16:18:25
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Mar 2021 16:18:17
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 18:50:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:42:44
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	19 Feb 2021 17:10:29
Signature has been broken.	Lauren Vigil (b) (4)	19 Feb 2021 17:10:25
User entered '0' reason for change: Data Entry Error	Lauren Vigil (b) (4)	19 Feb 2021 17:10:25
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 14:36:31

PRODUCTION RELEASE (v12.003
EAB) (1725)

1604 of 1956

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered '1'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered '0'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Michael Lewis (b) (4)	02 Apr 2021 06:15:16 20 Mar 2021 23:11:03
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:17:24
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' answered with 'updated' (Site from DM). DataPoint Un-verified.	Justine Velandria (b) (4) Justine Velandria (b) (4)	15 Mar 2021 16:19:11 15 Mar 2021 16:18:17
Signature has been broken.	(b) (4) Justine Velandria (b) (4)	15 Mar 2021 16:18:17
User entered '0' reason for change: Data Entry Error	(b) (4) Justine Velandria (b) (4)	15 Mar 2021 16:18:17
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Mar 2021 15:19:22 25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
Signature has been broken.	Lauren Vigil (b) (4)	19 Feb 2021 17:10:25
User entered '1' reason for change: Data Entry Error	(b) (4) Lauren Vigil (b) (4)	19 Feb 2021 17:10:25
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered '0'	Lauren Vigil (b) (4) (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered empty.	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User closed query 'Per DM CLR: Per SAE Narrative " BLOOD GLUCOSE >300 MG/DL.". However, this is not recorded in the procedures page. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 18:50:26
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
Query 'Per DM CLR: Per SAE Narrative " BLOOD GLUCOSE >300 MG/DL.". However, this is not recorded in the procedures page. Update as appropriate.' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	19 Feb 2021 17:10:32
Signature has been broken.	Lauren Vigil (b) (4)	19 Feb 2021 17:10:25
User entered 'CHEST PAIN REQUIRING ED VISIT ON 10/26. IMAGING AND EKG UNREMARKABLE.' reason for change: Data Entry Error	Lauren Vigil (b) (4)	19 Feb 2021 17:10:25
User opened query 'Per DM CLR: Per SAE Narrative " BLOOD GLUCOSE >300 MG/DL.". However, this is not recorded in the procedures page. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 14:38:52
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered 'CHEST PAIN REQUIRING ED VISIT ON 10/26. IMAGING AND EKG UNREMARKABLE. BLOOD GLUCOSE >300 MG/DL.'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
User entered '0'	System	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
User entered 'I'	System	30 Nov 2020 20:06:04

US3882016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:17:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:46

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered 'USA-US095-2021-mRNA-1273-P301000003'	System	02 Feb 2021 15:13:29
User entered 'New'	(b) (4), (b) (6)	02 Feb 2021 15:13:29

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User coded data point as SOC: Psychiatric disorders, HLGT: Schizophrenia and other psychotic disorders, HLT: Psychotic disorder NEC, PT: Substance-induced psychotic disorder, LLT: Substance-induced psychotic disorder - version MedDRA\\23.0.	Coder Import (b) (4)	02 Feb 2021 13:24:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Feb 2021 13:24:34
Data point term sent to Coder	System	01 Feb 2021 23:18:56
User entered 'Acute Substance induced psychosis'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered 'No (N)'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered 'No (N)'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30
	(b) (4)	

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User closed query 'Please confirm if the start date of this SAE is 20Nov2020 or 11Nov2020? Update date as necessary. ' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 01:37:58
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
Query 'Please confirm if the start date of this SAE is 20Nov2020 or 11Nov2020? Update date as necessary. ' answered with '11Nov2020' (Site from CRA).	Lauren Vigil (b) (4)	19 Feb 2021 17:11:46
User opened query 'Please confirm if the start date of this SAE is 20Nov2020 or 11Nov2020? Update date as necessary. ' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 06:03:21
User entered '11 Nov 2020'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered empty.	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
User entered empty.	System	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered 'No (N)'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered '7 Dec 2020'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30
	(b) (4)	

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered empty.	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
User entered empty.	System	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered 'Grade 4 (Grade 4)'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered '0'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered '0'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered 'I'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:38:25
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered '20 Nov 2020'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:38:28
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered '7 Dec 2020'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered 'No (N)'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered empty.	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered '0'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered '0'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered '0'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered 'Not Related (NOT RELATED)'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 23:19:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Feb 2021 23:19:01
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	01 Feb 2021 23:19:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Feb 2021 23:18:30
User entered empty.	System	01 Feb 2021 23:18:30
	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30
	(b) (4)	

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered 'Not Applicable (NOT APPLICABLE)'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	01 Feb 2021 23:19:01
User entered '1' reason for change: Data Entry Error	Lauren Vigil (b) (4)	01 Feb 2021 23:19:01
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	01 Feb 2021 23:18:30
User entered '0'	Lauren Vigil (b) (4) (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered '0'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered '0'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:38:45
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lauren Vigil (b) (4) (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:40:43
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
User entered empty.	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30
	(b) (4)	

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 01:38:42
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 16:08:11
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 16:08:08
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)	22 Feb 2021 16:08:02
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'unable to obtain' (Site from Safety).	Lauren Vigil (b) (4)	19 Feb 2021 17:12:27
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Unable to obtain' (Site from Safety).	Lauren Vigil (b) (4)	19 Feb 2021 17:12:17
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 'ND' (Site from Safety).	Lauren Vigil (b) (4)	19 Feb 2021 17:12:07
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 18:22:16

PRODUCTION RELEASE (v12.003
EAB) (1725)

1646 of 1956

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 18:22:05
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)	08 Feb 2021 18:21:54
User entered 'SUBJECT WAS TAKEN TO THE ER on 11/20/2020 BY VAPD DISORGANIZED AND MUMBLING THAT THEY WERE GOING TO KILL THEMSELVES. SUBJECT WAS ADMITTED FOR AN INVOLUNTARY HOLD. They were discharged 12/7/2020' reason for change: Data Entry Error	Lauren Vigil (b) (4)	01 Feb 2021 23:19:38
User entered 'Subject was taken to the ER by VAPD disorganized and mumbling that they were going to kill themselves. Subject was admitted for an involuntary hold.'	Lauren Vigil (b) (4)	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
User entered 'I'	System	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
User entered 'I'	System	01 Feb 2021 23:18:30

US3882016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:46
User entered '0'	System	01 Feb 2021 23:18:30

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:17:29

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:43:58
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
Signature has been broken.	Lauren Vigil (b) (4)	24 Sep 2020 18:19:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	24 Sep 2020 18:19:23
User signature succeeded.	Michael Lewis (b) (4)	12 Sep 2020 16:04:08
User entered 'No (N)'	Lauren Vigil (b) (4)	11 Sep 2020 19:57:09

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
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) (b) (4)	18 Nov 2020 16:11:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 16:11:07
Data point term sent to Coder	System	18 Nov 2020 16:09:44
Coding entries removed.	Lauren Vigil (b) (4) (b) (4)	18 Nov 2020 16:08:49
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
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) (b) (4)	24 Sep 2020 21:29:44
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 21:29:44
Data point term sent to Coder	System	24 Sep 2020 21:28:44
User entered 'Acetaminophen'	Lauren Vigil (b) (4) (b) (4)	24 Sep 2020 21:28:11

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 21:28:11

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User closed query 'Per DM CLR-RQ: Response noted. However, no there is still no corresponding MH or AE record that match this condition. Please review and either update to record the corresponding MH or AE or update Indication to record the actual MH or AE term as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 15:52:05
Query 'Per DM CLR-RQ: Response noted. However, no there is still no corresponding MH or AE record that match this condition. Please review and either update to record the corresponding MH or AE or update Indication to record the actual MH or AE term as appropriate. Otherwise, clarify. ' answered with 'No MH is recorded because no diagnosis has been made nor will the subject seek medical attention for the diagnosis to be made.' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	28 Jan 2021 22:35:13
User opened query 'Per DM CLR-RQ: Response noted. However, no there is still no corresponding MH or AE record that match this condition. Please review and either update to record the corresponding MH or AE or update Indication to record the actual MH or AE term as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 19:32:47
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:50:49
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain. Review and update medical history/AE diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:57:01
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain. Review and update medical history/AE diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	18 Nov 2020 16:09:00

PRODUCTION RELEASE (v12.003
EAB) (1725)

1654 of 1956

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
Signature has been broken.	Lauren Vigil (b) (4)	18 Nov 2020 16:08:49
	(b) (4)	
User entered 'general body PAIN' reason for change: Data Entry Error	Lauren Vigil (b) (4)	18 Nov 2020 16:08:49
	(b) (4)	
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain. Review and update medical history/AE diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:42:15
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Pain'	Lauren Vigil (b) (4)	24 Sep 2020 21:28:11
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	21 Apr 2021 17:38:04
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 00:20:27
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:50:49
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:57:08
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updateed' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	18 Nov 2020 16:10:46
Signature has been broken.	Lauren Vigil (b) (4) (b) (4)	18 Nov 2020 16:10:40
User entered '500' reason for change: Data Entry Error	Lauren Vigil (b) (4) (b) (4)	18 Nov 2020 16:10:40
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:42:26
User signature succeeded.	Michael Lewis (b) (4)	14 Oct 2020 00:16:26
Signature has been broken.	Lauren Vigil (b) (4) (b) (4)	13 Oct 2020 15:28:42
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered '560'	Lauren Vigil (b) (4) (b) (4)	24 Sep 2020 21:28:11

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'mg (mg)'	Lauren Vigil (b) (4)	24 Sep 2020 21:28:11

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:28:11

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'as needed (PRN)'	Lauren Vigil (b) (4)	24 Sep 2020 21:28:11

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:28:11

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	24 Sep 2020 21:28:11

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:28:11

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:28:11

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'l'	Lauren Vigil (b) (4)	24 Sep 2020 21:28:11

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	24 Sep 2020 21:28:11

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:28:11

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 21:28:11

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	24 Sep 2020 21:28:11

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	24 Sep 2020 21:28:11

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	24 Sep 2020 21:28:11

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Sep 2020 05:52:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Sep 2020 05:52:42
Data point term sent to Coder	System	24 Sep 2020 21:32:49
User entered 'Asipirin'	Lauren Vigil (b) (4)	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:50:49
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:57:13
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	18 Nov 2020 16:11:03
Signature has been broken.	Lauren Vigil (b) (4)	18 Nov 2020 16:10:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	18 Nov 2020 16:10:58
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:43:11
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'stroke/heart attack prevention'	Lauren Vigil (b) (4)	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered '81'	Lauren Vigil (b) (4)	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'mg (mg)'	Lauren Vigil (b) (4)	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'once daily (QD)'	Lauren Vigil (b) (4)	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'I'	Lauren Vigil (b) (4)	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '804 (804)'	System	24 Sep 2020 21:32:48

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
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) (b) (4)	29 Jan 2021 12:59:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 12:59:18
Data point term sent to Coder	System	28 Jan 2021 22:39:45
Coding entries removed.	Lauren Vigil (b) (4) (b) (4)	28 Jan 2021 22:38:56
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) (b) (4)	18 Nov 2020 16:15:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 16:15:07
Data point term sent to Coder	System	18 Nov 2020 16:13:50
Coding entries removed.	Lauren Vigil (b) (4) (b) (4)	18 Nov 2020 16:12:55
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
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) (b) (4)	24 Sep 2020 21:34:37
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 21:34:37
Data point term sent to Coder	System	24 Sep 2020 21:33:50
User entered 'Atorvastatin'	Lauren Vigil (b) (4) (b) (4)	24 Sep 2020 21:33:43

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 21:33:43

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User closed query 'Per DM CLR: Please review Indication and please update to provide the medical condition that this medication was used to treat, rather than the action of the medication. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 15:52:19
Query 'Per DM CLR: Please review Indication and please update to provide the medical condition that this medication was used to treat, rather than the action of the medication. Please update as appropriate or provide clarification. ' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	28 Jan 2021 22:39:01
Signature has been broken.	Lauren Vigil (b) (4) (b) (4)	28 Jan 2021 22:38:56
User entered 'MI - MYOCARDIAL INFARCTION' reason for change: Data Entry Error	Lauren Vigil (b) (4) (b) (4)	28 Jan 2021 22:38:56
User opened query 'Per DM CLR: Please review Indication and please update to provide the medical condition that this medication was used to treat, rather than the action of the medication. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 19:54:08
User closed query 'Per CDM re-query: Response is noted that site will confirm with subject for the medications on loglines 3 and 7. Please update where necessary per subject's response. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 04:31:24
Query 'Per CDM re-query: Response is noted that site will confirm with subject for the medications on loglines 3 and 7. Please update where necessary per subject's response. Thank you.' answered with 'yes' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	02 Dec 2020 16:23:25

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Response is noted that site will confirm with subject for the medications on loglines 3 and 7. Please update where necessary per subject's response. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 19:57:45
User closed query 'Per DM CLR: Please note there is no MH condition or 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 MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 19:57:45
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:50:49
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:57:41
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	18 Nov 2020 16:13:00
Signature has been broken.	Lauren Vigil (b) (4)	18 Nov 2020 16:12:55
User entered 'lowering CHOLESTEROL' reason for change: Data Entry Error	Lauren Vigil (b) (4)	18 Nov 2020 16:12:55
Query 'Per DM CLR: Please note there is no MH condition or 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 MH or AE eCRF. ' answered with 'no medical history for this con med. Will inquire with subject' (Site from DM).	Lauren Vigil (b) (4)	18 Nov 2020 16:12:25

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:46:34
User opened query 'Per DM CLR: Please note there is no MH condition or 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 MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:46:02
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'cholesterol'	Lauren Vigil (b) (4) (b) (4)	24 Sep 2020 21:33:43

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered '20'	Lauren Vigil (b) (4)	24 Sep 2020 21:33:43

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'mg (mg)'	Lauren Vigil (b) (4)	24 Sep 2020 21:33:43
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:33:43

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'once daily (QD)'	Lauren Vigil (b) (4)	24 Sep 2020 21:33:43

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:33:43
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	24 Sep 2020 21:33:43
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:33:43

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:33:43

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'I'	Lauren Vigil (b) (4)	24 Sep 2020 21:33:43

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	24 Sep 2020 21:33:43

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:33:43

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 21:33:43

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	24 Sep 2020 21:33:43

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	24 Sep 2020 21:33:43

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '804 (804)'	System	24 Sep 2020 21:33:43

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: ALOGLIPTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Sep 2020 21:41:43
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 21:41:43
Data point term sent to Coder	System	24 Sep 2020 21:40:04
User entered 'ALOGLIPTIN'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:12

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:12

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'diabetes'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:12

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Signature has been broken.	Lauren Vigil (b) (4)	01 Feb 2021 20:39:03
User entered '6.25' reason for change: Data Entry Error	Lauren Vigil (b) (4)	01 Feb 2021 20:39:03
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
Signature has been broken.	Lauren Vigil (b) (4)	30 Nov 2020 20:08:07
User entered '12.5' reason for change: Data Entry Error	Lauren Vigil (b) (4)	30 Nov 2020 20:08:07
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered '6.25'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:12

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'mg (mg)'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:12
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:39:12

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'once daily (QD)'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:12

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:39:12

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:12

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:39:12

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:39:12

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'l'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:12

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Signature has been broken.	Justine Velandria (b) (4)	29 Jan 2021 01:27:13
User entered 'No (N)' reason for change: Data Entry Error	Justine Velandria (b) (4)	29 Jan 2021 01:27:13
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:12

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '27 Oct 2020' reason for change: Data Entry Error	Justine Velandria (b) (4)	29 Jan 2021 01:33:34
Signature has been broken.	Justine Velandria (b) (4)	29 Jan 2021 01:27:13
User entered '07 Dec 2020' reason for change: Data Entry Error	Justine Velandria (b) (4)	29 Jan 2021 01:27:13
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:39:12

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:12

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	24 Sep 2020 21:39:12

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	24 Sep 2020 21:39:12

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '804 (804)'	System	24 Sep 2020 21:39:12

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 22:12:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 22:12:02
Data point term sent to Coder	System	25 Feb 2021 22:11:41
Data point term sent to Coder	System	25 Feb 2021 22:10:38
Coding entries removed.	Justine Velandria (b) (4) (b) (4)	25 Feb 2021 22:09:52
User signature succeeded.	Michael Lewis (b) (4) (b) (4)	26 Sep 2020 16:58:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:29:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:29:45
Data point term sent to Coder	System	24 Sep 2020 21:40:05
User entered 'TRAZODONE'	Lauren Vigil (b) (4) (b) (4)	24 Sep 2020 21:39:53

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:53

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	06 Mar 2021 23:05:40
User closed query 'Per DM CLR-RQ: Previous response noted. If the medication is used to aid in sleep, please update indication field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 09:06:16
Query 'Per DM CLR-RQ: Previous response noted. If the medication is used to aid in sleep, please update indication field as appropriate. ' answered with 'UPDATED TO INSOMNIA' (Site from DM).	Justine Velandria (b) (4)	25 Feb 2021 22:11:22
User entered 'INSOMNIA' reason for change: Data Entry Error	Justine Velandria (b) (4)	25 Feb 2021 22:10:51
Signature has been broken.	Justine Velandria (b) (4)	25 Feb 2021 22:09:52
User entered 'Chronic PTSD' reason for change: Data Entry Error	Justine Velandria (b) (4)	25 Feb 2021 22:09:52
User opened query 'Per DM CLR-RQ: Previous response noted. If the medication is used to aid in sleep, please update indication field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 21:17:57
User closed query 'Per DM CLR: Please update INDICATION to reflect the actual medical condition the med is being used to prevent/treat rather than the type of medication/mechanism of action. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 19:57:24
Query 'Per DM CLR: Please update INDICATION to reflect the actual medical condition the med is being used to prevent/treat rather than the type of medication/mechanism of action. Please review and update accordingly. ' answered with 'it is used to aid in sleep. Please review med history' (Site from DM).	Lauren Vigil (b) (4)	18 Nov 2020 16:15:47

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update INDICATION to reflect the actual medical condition the med is being used to prevent/treat rather than the type of medication/mechanism of action. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:08:21
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'sleep/mood'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:53
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Signature has been broken.	Lauren Vigil (b) (4)	01 Feb 2021 20:40:00
User entered '500' reason for change: Data Entry Error	Lauren Vigil (b) (4)	01 Feb 2021 20:40:00
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered '50'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:53

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'mg (mg)'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:53

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:39:53

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'once daily (QD)'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:53

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:39:53

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:53

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:39:53

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:39:53

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'I'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:53

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Signature has been broken.	Justine Velandria (b) (4)	29 Jan 2021 01:32:50
User entered 'No (N)' reason for change: Data Entry Error	Justine Velandria (b) (4)	29 Jan 2021 01:32:50
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:53

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Signature has been broken.	Justine Velandria (b) (4)	29 Jan 2021 01:32:50
User entered '8 Oct 2020' reason for change: Data Entry Error	Justine Velandria (b) (4)	29 Jan 2021 01:32:50
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:39:53

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 21:39:53

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	24 Sep 2020 21:39:53

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	24 Sep 2020 21:39:53

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '804 (804)'	System	24 Sep 2020 21:39:53

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 10:00:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 10:00:18
Data point term sent to Coder	System	28 Jan 2021 22:38:45
Coding entries removed.	Lauren Vigil (b) (4) (b) (4)	28 Jan 2021 22:38:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 15:19:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 15:19:43
Data point term sent to Coder	System	12 Dec 2020 00:10:41
Data point term sent to Coder	System	11 Dec 2020 23:53:38
Data point term sent to Coder	System	11 Dec 2020 23:52:38
Coding entries removed.	Lauren Vigil (b) (4) (b) (4)	11 Dec 2020 23:51:53
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 22:53:43

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	24 Sep 2020 22:53:43 24 Sep 2020 21:41:06
User entered 'METOPROLOL SUCCINATE'	Lauren Vigil (b) (4) (b) (4)	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User closed query 'Per CDM RQ : expand the abbreviation, Thank You' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 07:31:31
Query 'Per CDM RQ : expand the abbreviation, Thank You' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	28 Jan 2021 22:38:19
User entered 'MI - MYOCARDIAL INFARCTION' reason for change: Data Entry Error	(b) (4)	28 Jan 2021 22:38:12
User opened query 'Per CDM RQ : expand the abbreviation, Thank You' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 06:49:19
User closed query 'Per CDM: Re-query: Response noted. Please confirm if now information from subject is available. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 06:49:19
User entered 'MI' reason for change: Data Entry Error	Lauren Vigil (b) (4)	12 Dec 2020 00:10:04
User entered 'congestive heart failure' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 23:52:55
Signature has been broken.	Lauren Vigil (b) (4)	11 Dec 2020 23:51:53
User entered 'hypertension' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 23:51:53
Query 'Per CDM: Re-query: Response noted. Please confirm if now information from subject is available. Thank you. ' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	11 Dec 2020 23:51:45
User opened query 'Per CDM: Re-query: Response noted. Please confirm if now information from subject is available. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 11:04:47
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or 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 MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 11:04:47

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note there is no ongoing MH condition or 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 MH or AE eCRF. ' answered with 'no documented med history for med. Will inquire with subject' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	18 Nov 2020 16:16:19
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or 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 MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:09:18
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'blood pressure'	Lauren Vigil (b) (4) (b) (4)	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Signature has been broken.	Lauren Vigil (b) (4)	01 Feb 2021 20:41:36
User entered '25' reason for change: Data Entry Error	Lauren Vigil (b) (4)	01 Feb 2021 20:41:36
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered '75'	Lauren Vigil (b) (4)	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'mg (mg)'	Lauren Vigil (b) (4)	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'once daily (QD)'	Lauren Vigil (b) (4)	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'I'	Lauren Vigil (b) (4)	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '804 (804)'	System	24 Sep 2020 21:41:00

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:50:49
User closed query 'Per MM: Please review and update the medication name. Please update medication name as SERTRALINE and code it as N06AB. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:58:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:03:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:03:14
Data point term sent to Coder	System	18 Nov 2020 16:17:57
Coding entries removed.	Lauren Vigil (b) (4)	18 Nov 2020 16:17:05
User closed query 'Per MM, Please recode to N06AB' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:01:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 17:52:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 17:52:48
Data point term sent to Coder	System	17 Nov 2020 17:51:56
Query 'Per MM: Please review and update the medication name. Please update medication name as SERTRALINE and code it as N06AB. Thank you.' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	17 Nov 2020 17:51:04
User entered 'SERTRALINE' reason for change: Data Entry Error	Lauren Vigil (b) (4) (b) (4)	17 Nov 2020 17:50:59
User opened query 'Per MM: Please review and update the medication name. Please update medication name as SERTRALINE and code it as N06AB. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:15:40

PRODUCTION RELEASE (v12.003
EAB) (1725)

1766 of 1956

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	19 Oct 2020 16:00:37
Query 'Per MM, Please recode to N06AB' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	19 Oct 2020 16:00:14
Coding entries removed.	(b) (4)	
	Lauren Vigil (b) (4)	19 Oct 2020 16:00:08
	(b) (4)	
Signature has been broken.	Lauren Vigil (b) (4)	19 Oct 2020 16:00:08
	(b) (4)	
User entered 'N06AB' reason for change: Data Entry Error	Lauren Vigil (b) (4)	19 Oct 2020 16:00:08
	(b) (4)	
User opened query 'Per MM, Please recode to N06AB' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 14:34:13
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Sep 2020 05:37:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Sep 2020 05:37:46
	(b) (4)	
Data point term sent to Coder	System	24 Sep 2020 22:03:41
User entered 'SERTRALINE'	Lauren Vigil (b) (4)	24 Sep 2020 22:03:29
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 22:03:29

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:50:49
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:58:51
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	18 Nov 2020 16:17:12
Signature has been broken.	Lauren Vigil (b) (4)	18 Nov 2020 16:17:05
User entered 'MOOD (Chronic post-traumatic stress disorder)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	18 Nov 2020 16:17:05
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:09:42
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'mood'	Lauren Vigil (b) (4)	24 Sep 2020 22:03:29

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered '50'	Lauren Vigil (b) (4)	24 Sep 2020 22:03:29

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'mg (mg)'	Lauren Vigil (b) (4)	24 Sep 2020 22:03:29

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 22:03:29

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'once daily (QD)'	Lauren Vigil (b) (4)	24 Sep 2020 22:03:29

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 22:03:29

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	24 Sep 2020 22:03:29

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 22:03:29

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 22:03:29

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'l'	Lauren Vigil (b) (4)	24 Sep 2020 22:03:29

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Signature has been broken.	Lauren Vigil (b) (4)	01 Feb 2021 20:45:38
User entered 'No (N)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	01 Feb 2021 20:45:38
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	24 Sep 2020 22:03:29

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Signature has been broken.	Lauren Vigil (b) (4)	01 Feb 2021 20:45:38
User entered '06 Jan 2021' reason for change: Data Entry Error	Lauren Vigil (b) (4)	01 Feb 2021 20:45:38
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 22:03:29

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 22:03:29

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	24 Sep 2020 22:03:29

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	24 Sep 2020 22:03:29

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '804 (804)'	System	24 Sep 2020 22:03:29

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 06:09:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 06:09:12
Data point term sent to Coder	System	18 Nov 2020 16:17:57
Coding entries removed.	Lauren Vigil (b) (4) (b) (4)	18 Nov 2020 16:17:53
User signature succeeded.	Michael Lewis (b) (4) (b) (4)	26 Sep 2020 16:58:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 22:05:43
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 22:05:43
Data point term sent to Coder	System	24 Sep 2020 22:04:42
User entered 'GABAPENTIN'	Lauren Vigil (b) (4) (b) (4)	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:50:49
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain. Review and update medical history/AE diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:58:56
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain. Review and update medical history/AE diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	18 Nov 2020 16:17:58
Signature has been broken.	Lauren Vigil (b) (4)	18 Nov 2020 16:17:53
User entered 'general body PAIN' reason for change: Data Entry Error	Lauren Vigil (b) (4)	18 Nov 2020 16:17:53
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain. Review and update medical history/AE diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:10:13
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'pain'	Lauren Vigil (b) (4)	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered '600'	Lauren Vigil (b) (4)	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'mg (mg)'	Lauren Vigil (b) (4)	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'as needed (PRN)'	Lauren Vigil (b) (4)	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'l'	Lauren Vigil (b) (4)	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:58:20
User entered 'No (N)'	Lauren Vigil (b) (4)	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	24 Sep 2020 22:04:08

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 09:50:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 09:50:15
Data point term sent to Coder	System	29 Jan 2021 01:25:48
User entered 'HYDROXYZINE'	Justine Velandria (b) (4)	29 Jan 2021 01:25:35
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'Yes (Y)'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:25:35

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'AS NEEDED FOR INSOMNIA'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:25:35

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '50'	Justine Velandria (b) (4)	29 Jan 2021 01:25:35

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'mg (mg)'	Justine Velandria (b) (4)	29 Jan 2021 01:25:35
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:25:35
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	06 Mar 2021 23:05:40
User closed query 'Per DM CLR: The indication signifies "AS NEEDED". However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 09:07:11
Query 'Per DM CLR: The indication signifies "AS NEEDED". However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' answered with 'UPDATED' (Site from DM).	Justine Velandria (b) (4)	25 Feb 2021 22:11:58
Signature has been broken.	Justine Velandria (b) (4)	25 Feb 2021 22:11:51
User entered 'as needed (PRN)' reason for change: Data Entry Error	Justine Velandria (b) (4)	25 Feb 2021 22:11:51
User opened query 'Per DM CLR: The indication signifies "AS NEEDED". However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 21:18:39
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'four times daily (QID)'	Justine Velandria (b) (4)	29 Jan 2021 01:25:35

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:25:35
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'Oral (ORAL)'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:25:35

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:25:35
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '7 Dec 2020'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:25:35

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '0'	Justine Velandria (b) (4)	29 Jan 2021 01:25:35

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'Yes (Y)'	Justine Velandria (b) (4)	29 Jan 2021 01:25:35
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:25:35

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'No (N)'	Justine Velandria (b) (4)	29 Jan 2021 01:25:35
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	25 Feb 2021 22:11:51
User entered '4'	System	29 Jan 2021 01:25:35

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	25 Feb 2021 22:11:51
User entered 'I'	System	29 Jan 2021 01:25:35

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	25 Feb 2021 22:11:51
User entered '804 (804)'	System	29 Jan 2021 01:25:35

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
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)	29 Jan 2021 01:27:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 01:27:09
Data point term sent to Coder	System	29 Jan 2021 01:26:49
User entered 'METFORMIN'	Justine Velandria (b) (4)	29 Jan 2021 01:26:45
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 01:27:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 01:27:25
User entered 'No (N)' reason for change: Data Entry Error	Justine Velandria (b) (4)	29 Jan 2021 01:27:25
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 01:26:45
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:26:45

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'DIABETES'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:26:45

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '1000'	Justine Velandria (b) (4)	29 Jan 2021 01:26:45

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'mg (mg)'	Justine Velandria (b) (4)	29 Jan 2021 01:26:45
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:26:45

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'other (OTHER)' reason for change:	Justine Velandria (b) (4)	29 Jan 2021 01:28:35
Data Entry Error	(b) (4)	
User entered 'once daily (QD)'	Justine Velandria (b) (4)	29 Jan 2021 01:26:45
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'EVERY EVENING' reason for change: Data Entry Error	Justine Velandria (b) (4)	29 Jan 2021 01:28:35
User entered empty.	(b) (4)	
	Justine Velandria (b) (4)	29 Jan 2021 01:26:45
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'Oral (ORAL)'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:26:45

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:26:45

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '7 Dec 2020'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:26:45

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '0'	Justine Velandria (b) (4)	29 Jan 2021 01:26:45

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'Yes (Y)'	Justine Velandria (b) (4)	29 Jan 2021 01:26:45
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:26:45

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'No (N)'	Justine Velandria (b) (4)	29 Jan 2021 01:26:45

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	29 Jan 2021 01:28:35
User entered 'I'	System	29 Jan 2021 01:26:45

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	29 Jan 2021 01:28:35
User entered 'I'	System	29 Jan 2021 01:26:45

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	29 Jan 2021 01:28:35
User entered '804 (804)'	System	29 Jan 2021 01:26:45

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
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)	29 Jan 2021 01:29:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 01:29:09
Data point term sent to Coder	System	29 Jan 2021 01:28:49
User entered 'METFORMIN'	Justine Velandria (b) (4)	29 Jan 2021 01:28:20
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'No (N)'	Justine Velandria (b) (4)	29 Jan 2021 01:28:20
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'DIABETES'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:28:20

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '500'	Justine Velandria (b) (4)	29 Jan 2021 01:28:20

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'mg (mg)'	Justine Velandria (b) (4)	29 Jan 2021 01:28:20
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:28:20
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'other (OTHER)'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:28:20

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'EVERY MORNING'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:28:20

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'Oral (ORAL)'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:28:20

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:28:20
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '7 Dec 2020'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:28:20

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '0'	Justine Velandria (b) (4)	29 Jan 2021 01:28:20

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'Yes (Y)'	Justine Velandria (b) (4)	29 Jan 2021 01:28:20
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:28:20

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'No (N)'	Justine Velandria (b) (4)	29 Jan 2021 01:28:20
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	29 Jan 2021 01:28:20

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	29 Jan 2021 01:28:20

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered empty.	System	29 Jan 2021 01:28:20

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:29:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:29:47
Data point term sent to Coder	System	25 Feb 2021 22:13:51
Coding entries removed.	Justine Velandria (b) (4) (b) (4)	25 Feb 2021 22:12:57
User signature succeeded.	Michael Lewis (b) (4) (b) (4)	08 Feb 2021 02:49:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 13:50:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 13:50:29
Data point term sent to Coder	System	29 Jan 2021 01:29:50
User entered 'QUETIAPINE FUMARATE'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:29:31

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'No (N)'	Justine Velandria (b) (4)	29 Jan 2021 01:29:31
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	06 Mar 2021 23:05:40
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 09:47:37
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' answered with 'psychotic disorder with delusions' (Site from DM).	Justine Velandria (b) (4) (b) (4)	25 Feb 2021 22:13:07
Signature has been broken.	Justine Velandria (b) (4) (b) (4)	25 Feb 2021 22:12:57
User entered 'psychotic disorder with delusions' reason for change: Data Entry Error	Justine Velandria (b) (4) (b) (4)	25 Feb 2021 22:12:57
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 21:20:12
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'MOOD'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:29:31

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '400'	Justine Velandria (b) (4)	29 Jan 2021 01:29:31
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'mg (mg)'	Justine Velandria (b) (4)	29 Jan 2021 01:29:31
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:29:31

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	13 Mar 2021 13:02:00
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	08 Mar 2021 17:42:02
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	08 Mar 2021 17:41:48
Signature has been broken.	Lauren Vigil (b) (4)	08 Mar 2021 17:41:48
User entered 'once daily (QD)' reason for change:	(b) (4)	
Data Entry Error	Lauren Vigil (b) (4)	08 Mar 2021 17:41:48
User signature succeeded.	(b) (4)	
	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'other (OTHER)'	Justine Velandria (b) (4)	29 Jan 2021 01:29:31
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	13 Mar 2021 13:02:00
User closed query 'Per CDM: Per page 54 of CCGs v5.0, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "once daily" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 15:40:05
Query 'Per CDM: Per page 54 of CCGs v5.0, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "once daily" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'Updated.' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	08 Mar 2021 17:42:11
Signature has been broken.	Lauren Vigil (b) (4) (b) (4)	08 Mar 2021 17:42:02
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4) (b) (4)	08 Mar 2021 17:42:02
User opened query 'Per CDM: Per page 54 of CCGs v5.0, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "once daily" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 12:08:42
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'AT BEDTIME'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:29:31

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'Oral (ORAL)'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:29:31

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:29:31
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '07 Dec 2020'	Justine Velandria (b) (4)	29 Jan 2021 01:29:31

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '0'	Justine Velandria (b) (4)	29 Jan 2021 01:29:31
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'Yes (Y)'	Justine Velandria (b) (4)	29 Jan 2021 01:29:31
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:29:31

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'No (N)'	Justine Velandria (b) (4)	29 Jan 2021 01:29:31

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	08 Mar 2021 17:41:48
User entered empty.	System	29 Jan 2021 01:29:31

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	08 Mar 2021 17:41:48
User entered empty.	System	29 Jan 2021 01:29:31

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '804 (804)'	System	08 Mar 2021 17:41:48
User entered empty.	System	29 Jan 2021 01:29:31

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 10:13:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 10:13:16
Data point term sent to Coder	System	29 Jan 2021 01:30:50
User entered 'SEMAGLUTIDE 0.25 MG/1.5 ML'	Justine Velandria (b) (4)	29 Jan 2021 01:30:44
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'No (N)'	Justine Velandria (b) (4)	29 Jan 2021 01:30:44

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'DIABETES'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:30:44

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '0.25'	Justine Velandria (b) (4)	29 Jan 2021 01:30:44

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'mg (mg)'	Justine Velandria (b) (4)	29 Jan 2021 01:30:44

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:30:44

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'every week (QS)'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:30:44

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:30:44
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'Subcutaneous (SUBCUTANEOUS)'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:30:44

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:30:44
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '7 Dec 2020'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:30:44

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '0'	Justine Velandria (b) (4)	29 Jan 2021 01:30:44

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'Yes (Y)'	Justine Velandria (b) (4)	29 Jan 2021 01:30:44
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:30:44

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'No (N)'	Justine Velandria (b) (4)	29 Jan 2021 01:30:44

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	29 Jan 2021 01:30:44

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	29 Jan 2021 01:30:44

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '803 (803)'	System	29 Jan 2021 01:30:44

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN ALCOHOL DEPENDENCE, PRODUCT: NALTREXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 22:15:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 22:15:02
Data point term sent to Coder	System	25 Feb 2021 22:14:52
Coding entries removed.	Justine Velandria (b) (4) (b) (4)	25 Feb 2021 22:14:05
User signature succeeded.	Michael Lewis (b) (4) (b) (4)	08 Feb 2021 02:49:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN ALCOHOL DEPENDENCE, PRODUCT: NALTREXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 14:14:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 14:14:28
Data point term sent to Coder	System	29 Jan 2021 01:32:51
User entered 'NALTREXONE'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:32:27

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'No (N)'	Justine Velandria (b) (4)	29 Jan 2021 01:32:27

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	06 Mar 2021 23:05:40
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 09:49:19
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' answered with 'alcohol dependence' (Site from DM).	Justine Velandria (b) (4)	25 Feb 2021 22:14:13
Signature has been broken.	(b) (4)	
User entered 'alcohol dependence' reason for change: Data Entry Error	Justine Velandria (b) (4)	25 Feb 2021 22:14:05
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' (Site from DM).	(b) (4)	
User signature succeeded.	Michael Lewis (b) (4)	25 Feb 2021 21:22:01
User entered 'CRAVINGS'	Justine Velandria (b) (4)	25 Feb 2021 21:22:01
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '50'	Justine Velandria (b) (4)	29 Jan 2021 01:32:27

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'mg (mg)'	Justine Velandria (b) (4)	29 Jan 2021 01:32:27
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:32:27

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'once daily (QD)'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:32:27

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:32:27

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'Oral (ORAL)'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:32:27

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:32:27

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '7 Dec 2020'	Justine Velandria (b) (4) (b) (4)	29 Jan 2021 01:32:27

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '0'	Justine Velandria (b) (4)	29 Jan 2021 01:32:27
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'Yes (Y)'	Justine Velandria (b) (4)	29 Jan 2021 01:32:27
	(b) (4)	

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered empty.	Justine Velandria (b) (4)	29 Jan 2021 01:32:27

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:55:20
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'No (N)'	Justine Velandria (b) (4)	29 Jan 2021 01:32:27

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	29 Jan 2021 01:32:27

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '1'	System	29 Jan 2021 01:32:27

US3882016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User entered '804 (804)'	System	29 Jan 2021 01:32:27

US3882016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:17:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 06:32:09
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
Signature has been broken.	Lauren Vigil (b) (4)	30 Nov 2020 20:06:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	30 Nov 2020 20:06:21
User signature succeeded.	Michael Lewis (b) (4)	12 Sep 2020 16:04:08
User entered 'No (N)'	Lauren Vigil (b) (4)	11 Sep 2020 19:57:15

US3882016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:17:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 06:32:20
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered '26 Oct 2020'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:39

US3882016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:17:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	22 Feb 2021 23:26:17
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 21:53:06
User closed query 'Please update term to just 'EKG'. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 21:52:58
Query 'Please update term to just 'EKG'. Thank you. ' answered with 'updated' (Site from CRA).	Lauren Vigil (b) (4)	22 Feb 2021 21:41:51
Signature has been broken.	(b) (4)	
	Lauren Vigil (b) (4)	22 Feb 2021 21:41:43
	(b) (4)	
User entered 'EKG' reason for change: Data Entry Error	Lauren Vigil (b) (4)	22 Feb 2021 21:41:43
	(b) (4)	
User opened query 'Please update term to just 'EKG'. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 21:16:41
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:50
DataPoint Un-verified.	Lauren Vigil (b) (4)	19 Feb 2021 17:12:58
	(b) (4)	
Signature has been broken.	Lauren Vigil (b) (4)	19 Feb 2021 17:12:58
	(b) (4)	
User entered 'EKG Chest Pain' reason for change: Data Entry Error	Lauren Vigil (b) (4)	19 Feb 2021 17:12:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 06:32:22
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered 'EKG'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:39
	(b) (4)	

US3882016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:17:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 21:53:32
User closed query 'Please update Indication term to 'Diagnostic for Chest Pain' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 21:53:28
Query 'Please update Indication term to 'Diagnostic for Chest Pain' answered with 'indication cannot be updated as this is not an option on the drop down menu' (Site from CRA).	Lauren Vigil (b) (4)	22 Feb 2021 21:42:08
User opened query 'Please update Indication term to 'Diagnostic for Chest Pain' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 21:15:33
User closed query 'Please consider updating term to "chest pain" since date correlates to an Adverse Event on the same day. ' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 21:15:33
Query 'Please consider updating term to "chest pain" since date correlates to an Adverse Event on the same day. ' answered with 'updated' (Site from CRA).	Lauren Vigil (b) (4)	19 Feb 2021 17:13:06
User opened query 'Please consider updating term to "chest pain" since date correlates to an Adverse Event on the same day. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 06:35:00
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered 'Diagnostic (DIAGNOSTIC)'	Lauren Vigil (b) (4)	30 Nov 2020 20:06:39

US3882016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:17:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 06:35:05
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:43:24
User entered empty.	Lauren Vigil (b) (4)	30 Nov 2020 20:06:39

US3882016

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:17:29

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	20 Mar 2021 23:11:03
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:54:35
User entered '4 Mar 2021'	Lauren Vigil (b) (4)	17 Mar 2021 16:53:07
	(b) (4)	

US3882016

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:17:29

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	20 Mar 2021 23:11:03
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:54:38
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Lauren Vigil (b) (4) (b) (4)	17 Mar 2021 16:53:07

US3882016

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:17:29

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	20 Mar 2021 23:11:03
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:54:40
User entered 'Non compliant'	Lauren Vigil (b) (4)	17 Mar 2021 16:53:07

US3882016

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:17:29

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	20 Mar 2021 23:11:03
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:54:42
User entered empty.	Lauren Vigil (b) (4)	17 Mar 2021 16:53:07
	(b) (4)	

US3882016

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:17:29

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	20 Mar 2021 23:11:03
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:54:42
User entered empty.	Lauren Vigil (b) (4)	17 Mar 2021 16:53:07
	(b) (4)	

US3882016

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:17:29

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	20 Mar 2021 23:11:03
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:54:42
User entered empty.	Lauren Vigil (b) (4)	17 Mar 2021 16:53:07
	(b) (4)	

US3882016

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:17:29

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	20 Mar 2021 23:11:03
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:54:42
User entered empty.	Lauren Vigil (b) (4)	17 Mar 2021 16:53:07
	(b) (4)	

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'USA-US095-2021-MRNA-1273-P301000003'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'Yes (Y)'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'No (N)'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'No (N)'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'Yes (Y)'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'No (N)'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'No (N)'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'No (N)'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'Michael'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'Lewis'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:04:00

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'US'	System	02 Feb 2021 15:15:49

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'I'	System	02 Feb 2021 15:15:49

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'USA-US095-2021-MRNA-1273-P301000003'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'Yes (Y)'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'No (N)'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'No (N)'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'Yes (Y)'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'No (N)'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'No (N)'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'No (N)'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'Michael'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'Lewis'	System	02 Feb 2021 15:13:29

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:04:00

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:04:00

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:04:00

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'US'	System	02 Feb 2021 15:15:49

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered 'I'	System	02 Feb 2021 15:15:49

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:17:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
User entered '02/Feb/2021 10:15'	System	02 Feb 2021 15:15:49

US3882016

Folder: SAE USA-US095-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:17:29

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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:04:00
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 21:11:19
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:49:23
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:15:53
User entered 'I'	(b) (4), (b) (6)	02 Feb 2021 15:15:49